GREAT LAKES
DREDGED MATERIAL TESTING AND EVALUATION MANUAL

APPENDIX E
QUALITY ASSURANCE GUIDANCE

prepared by:

Patricia M. Boone
USEPA, Region 5

Jan A. Miller
USACE, Great Lakes & Ohio River Division

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ATTACHMENTS

1. PURPOSE AND APPLICABILITY

This appendix provides guidance on the quality assurance program for the testing and evaluation of dredged material proposed for discharge into the Great Lakes. Section 2 of this appendix defines and discusses the principal components of a "quality system" for an organization. Section 3 summarizes the quality assurance program for Great Lakes dredged material testing and evaluation.

This quality assurance guidance is intended for use by the USACE in contracts for dredged material data collection. This guidance is also intended for use by Section 404 permit applicants as the minimum quality assurance requirements for data which the USACE will accept for a permit determination regarding the discharge of dredged material to waters of the U.S.

Specific protocols for project design, sample collection, handling and storage, sample and data custody, field and laboratory analysis and reporting, and data assessment and interpretation are described in the Great Lakes Dredged Materials Testing and Evaluation Manual (GLTEM) and Appendices D, F and G.

2. QUALITY SYSTEM COMPONENTS

The complexity of environmental data collection demands that a systematic process and structure be established to provide decision makers with the necessary confidence in the quality of data produced for decisions as well as the means to determine when the data are not fully usable. This section will define the components of such a systematic process and the structure for an organization, termed a quality system.

2.1 Quality Systems

A **quality system** provides the framework for planning, implementing and assessing work performed by and/or for an organization. A quality system consists of the policies, principles, authority, objectives, responsibilities, accountability, and implementation plan for ensuring quality in work processes, products, and services. The principal components of a quality system include:

- quality assurance management plans (Section 2.2),
- quality assurance program plans (Section 2.3),
- data quality objectives planning process (Section 2.4),
- quality assurance project plans (Section 2.5),
- standard operating procedures (Section 2.6),
- data quality assessments (Section 2.7), and
- QA program assessments (Section 2.8).

Quality assurance (QA) is an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvements to ensure that a process, item, or service is of the type and quality needed.

Quality control (QC) is the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements.

QC for environmental data collection projects can be divided into two basic types: sample performance QC and method performance QC. Sample performance QC provided quantitative information on the quality of the sample. Method performance QC provides quantitative information on the quality of the method during implementation for a given sample.

2.2 Quality Assurance Management Plan

As a first step to establishing a quality system, each organization documents their quality assurance policy and management structure in a **quality assurance management plan (QAMP)**. The QAMP provides the blueprint for how an individual agency will plan, implement and assess the quality of the environmental work performed by or on behalf of an organization. The QAMP consists of the following ten elements:

- quality management and organization,
- quality system,
- personnel qualification and training,
- procurement of items and services,
- quality documentation and records,
- use of computer hardware and software,
- quality planning,
- quality implementation of work processed,
- quality assessment and response, and
- quality improvement.

Relevant QAMPs applicable to Great Lakes dredged material testing and evaluation are discussed in Section 3.1.

2.3 Quality Assurance Program Plans

Quality assurance program plans are written to further define the management structure and applicable QA requirements for individual programs (e.g., NPDES, Superfund, TSCA) within the organization, according to the regulations and policies for each environmental program. The quality assurance program plan institutes processes, recommends procedures, sets minimum standards, and documents how and when QA and QC are applied at

the technical/project level during planning, implementation, and assessment.

Section 3 of this appendix presents the quality assurance program plan for Great Lakes dredged material testing and evaluation.

2.4 Data Quality Objective Process

The data quality objective process is used to establish data collection requirements for environmental programs and projects within an organization. The iterative 7-step data quality objective process provides the framework for planners to focus their planning efforts (USEPA 1993d). It is almost always necessary to revisit previous steps.

The data quality objective process differs from historical planning approaches in that acceptable probabilities of making false negative and false positive decisions are set prior to the project, and the study is designed such that data collected can verify that these probabilities were achieved. Decision error is a product of the uncertainty in results. Uncertainty is determined by data quality and quantity. Some of the common sources of uncertainty are listed in table E-1.

Measuring and allocating overall uncertainty typically requires pilot studies to estimate environmental heterogeneity to design an effective sampling program, and sufficient data to render sampling/analytical bias and imprecision less than environmental heterogeneities (i.e. define the magnitude of uncertainty and the confidence level in the magnitude of uncertainty observed).

Neither pilot studies nor statistical project designs are possible, or arguably, appropriate for individual dredged material evaluations. For dredged material testing, the quantification of uncertainty is still in the realm of research and development. Therefore, decisions will continue to be based on "best professional judgement" rather than "statistical uncertainty". This does not mean the data quality objective process cannot be used. The probability of discharging contaminated dredged material to waters of the U.S. (i.e., a false negative decision) is difficult to determine, but an attempt to control uncertainty has been made by setting minimum specifications and controlling protocols for collecting environmental data for dredged material evaluations.

2.4.1 Data quality objectives

Data quality objectives (DQOs) are qualitative and

quantitative statements derived from the outputs of the steps of the data quality objective process which specify the program/study objectives, domain, limitations, the most appropriate type of data to collect, use of the data (the decision), decision criteria (action levels), and the levels of decision error that will be acceptable. The general DQOs for Great Lakes dredged material testing and evaluation are presented throughout the GLTEM and appendices, and are summarized in Section 3.

Table E-1 Common Sources of Error

Sources of Overall Error (in decreasing order of importance)
- Pollutant distribution
- Sample design and collection (varies w/ analyte and matrix)
- Sample procedures and handling
- Laboratory sample preparation
- Laboratory sample analysis
- Data handling

Sample Design and Collection Errors

- Not homogeneously distributed
- Unrepresentative number of samples
- Unrepresentative spots sampled
- Migration not accounted for
- Wrong type of sampling (e.g. random)

Common Sampling Procedure Errors
- Inappropriate equipment
- Cross contamination
- Disturbs composition

Laboratory Preparation and Analytical Errors
- Subsampling errors
- Lose sample (all or part)
- Contamination
- Wrong protocol
- Acceptance limits determined for different matrix
- Wrong calibrate or reference used

2.4.2 Data quality indicators

Data quality indicators (DQIs) are quantitative statistics and qualitative descriptors that are used to define "the most appropriate data to collect" and to assess the degree of acceptability or utility of the data collected to the user. Project DQIs are set as part of Step 3 of the data quality objective process. Historically, DQIs include sensitivity,

precision, accuracy, completeness, representativeness, and comparability. A detailed discussion of these indicators is provided in Attachment E-1.

DQIs apply to sample designs, all types of field and laboratory measurements, as well as "secondary" data produced by modeling or manipulation of field and laboratory measurements. It is critical for the quantitative DQIs (i.e. sensitivity, precision, accuracy, and completeness) that appropriate means/processes be used to measure/estimate the DQIs and that acceptance criteria for DQIs be determined using the means/processes that will be used in the project.

The DQIs for Great Lakes dredged material testing and evaluation are presented in Section 3.4.

2.5 Standard Operating Procedures

Standard operating procedures (SOPs) are written documents that detail the method of operation, analysis, or action with prescribed techniques and steps. Consistency and thoroughness are best maintained by following written SOPs. Documentation ensures all requirements were met and provides proof that the procedure was conducted properly if questions arise later.

SOPs are officially approved as the method for performing certain routine or repetitive tasks. SOPs should be periodically reviewed and updated as necessary, and may be modified to fit the individual sampling and analysis activities of specific projects. Guidance on preparing SOPs is provided as Attachment E-2.

The "Inland Testing Manual" (USEPA/USACE 1998) contains a number of technical appendices which will function as SOPs for procedures and analyses required for making a 404(b)(1) contaminant determination:

Appendix B: Guidance for evaluation of effluent discharges from confined disposal facilities
Appendix C: Evaluation of mixing (STFATE model)
Appendix D: Statistical methods

This, and other appendices to the GLTEM provide guidance on sediment sampling and handling (Appendix D), physical and chemical analyses (Appendix F), and biological effects-based tests (Appendix G). The GLTEM is intended to serve as SOPs for the majority of dredged material testing and evaluation. Guidance on SOPs for modified or new procedures for Great Lakes dredged material evaluations is provided in Section 3.5.

2.6 Quality Assurance Project Plans

A **quality assurance project plans** (QAPP) is the principal product of the project planning process inasmuch as it integrates all technical and quality aspects for the life-cycle of the project, including planning, implementation and assessment.

During project planning, the QAPP documents the outputs of the data quality objective process and is used for project coordination and oversight. During project implementation, the QAPP serves as a blueprint for project personnel. The following are the 16 traditional elements of a QAPP:

1) Title and signature page(s).
2) Table of contents.
3) Project description.
4) Organization and responsibility.
5) Quality assurance objectives.
6) Sampling procedures.
7) Sample and data documentation and custody.
8) Calibration.
9) Methods.
10) Internal quality controls.
11) Data reduction, validation, and reporting.
12) Performance and systems audits.
13) Preventive maintenance.
14) Data quality assessment and usability.
15) Corrective action.
16) Quality assurance reports to management.

The QAPP is the primary resource for assessing the usability of and interpreting project results. The QAPP may be supplemented by previously prepared planning documents or concurrently prepared procurement documents. A modified QAPP format for Great Lakes dredged material evaluations is discussed in Section 3.6. Additional guidance on preparing QAPPs is in USEPA (1991c; 1993a).

2.7 Data Quality Assessment

Assessment is the evaluation process used to measure the performance or effectiveness of a system and its elements. Assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection or surveillance.

Once the DQO process has been completed, the planning team will have the information needed to choose the sampling design that best meets the needs of their study. The needs of the planning team have not been fully met, however, until the

sampling data are analyzed to ensure that any decision made from the data will meet project specifications. This analysis is part of a related process called **data quality assessment (DQA)**.

The DQA process is used to assess the scientific and statistical quality of data for a specified purpose. During the DQA process, data is analyzed scientifically for technical anomalies and to judge if the context of the data is correct. At the same time, the data may be evaluated statistically. The outcome of DQA analysis will determine whether a decision can be made using the existing data or whether additional sampling data must be collected. The DQA process is also useful for determining whether a sampling design is appropriate for similar studies.

DQA guidance for Great Lakes dredged material testing and evaluation is provided in Section 3.7.

2.8 Quality Assurance Program Assessments

There are three types of assessments of a QA program: reviews, inspections and audits. **Reviews** and **inspections** are assessments of the conformance of systems to qualitative requirements or specifications. **Audits** are assessments of the conformance of systems to quantitative specifications.

Management systems reviews (MSRs) assess the effectiveness of the implementation of the approved QA program. These reviews consider linkages across organizational lines and can be used to discern areas requiring improved guidance. The effectiveness of the management system is generally measured using judgement based on non-technical information assembled and analyzed. Management systems reviews should be performed on at least an annual basis and should be conducted according to the goals and procedures stated in the organization's QAMP. Guidance on preparing and conducting MSRs is provided in USEPA (1994a). Refer to the QAMPs listed in Section 3.1 for more information on management system reviews that are part of the QA program for Great Lakes dredged material testing and evaluation.

Systems inspections assess project QC activities and environmental data collection systems. A systems audit qualitatively evaluates all components of the measurement system to determine proper selection, maintenance, and use. This audit includes a careful evaluation of both field and laboratory quality control procedures and records. General guidance for planning and conducting technical systems audits is provided in USEPA (1993f).

Performance audits quantitatively evaluate the field and/or laboratory personnel's performance and the instrumentation or analytical systems used. Performance audits evaluate the accuracy and precision of the total measurement system with samples of known composition or behavior.

Audits of data quality (ADQ) are a qualitative evaluation of the documentation and procedures associated with environmental measurements to verify that the resulting data are of acceptable quality. ADQs address whether or not sufficient information exists for the data sets to support data quality assessment.

Quality assurance program assessments for Great Lakes dredged material testing and evaluation are discussed in Section 3.8.

3. QUALITY ASSURANCE PROGRAM FOR GREAT LAKES DREDGED MATERIAL TESTING AND EVALUATION

The program for regulating the discharge of dredged material into the U.S. waters of the Great Lakes basin is managed by the USACE in cooperation with the USEPA and Great Lakes States. USACE district offices in Buffalo, Chicago, Detroit and St. Paul administer the Section 404 permit program. The USACE districts at Buffalo, Chicago and Detroit also conduct the maintenance dredging of Federal navigation projects in the Great Lakes. The USACE District Engineer is ultimately responsible for making determinations of compliance with Section 404. State regulatory agencies are responsible for issuing water quality certifications for dredged material discharges under Section 401.

Environmental data is collected as part of a 404(b)(1) evaluation to make a contaminant determination. The "Inland Testing Manual" and the GLTEM utilize a tiered testing approach to identify the data needed to determine compliance. Great Lakes dredged material testing requirements are consistent with the "Inland Testing Manual," but have been tailored to the needs of the Great Lakes. The GLTEM provides more specific testing requirements based on physical, chemical and biological conditions representative of the Great Lakes. For example, laboratory methods for chemical analysis of sediments were selected based, in part, on their ability to achieve target detection limits representative of background levels in the Great Lakes sediments.

The USEPA and USACE, in developing the GLTEM and Appendices have formulated a quality assurance program for Great Lakes dredged material testing and evaluation. An overview of this program is shown on figure E-1.

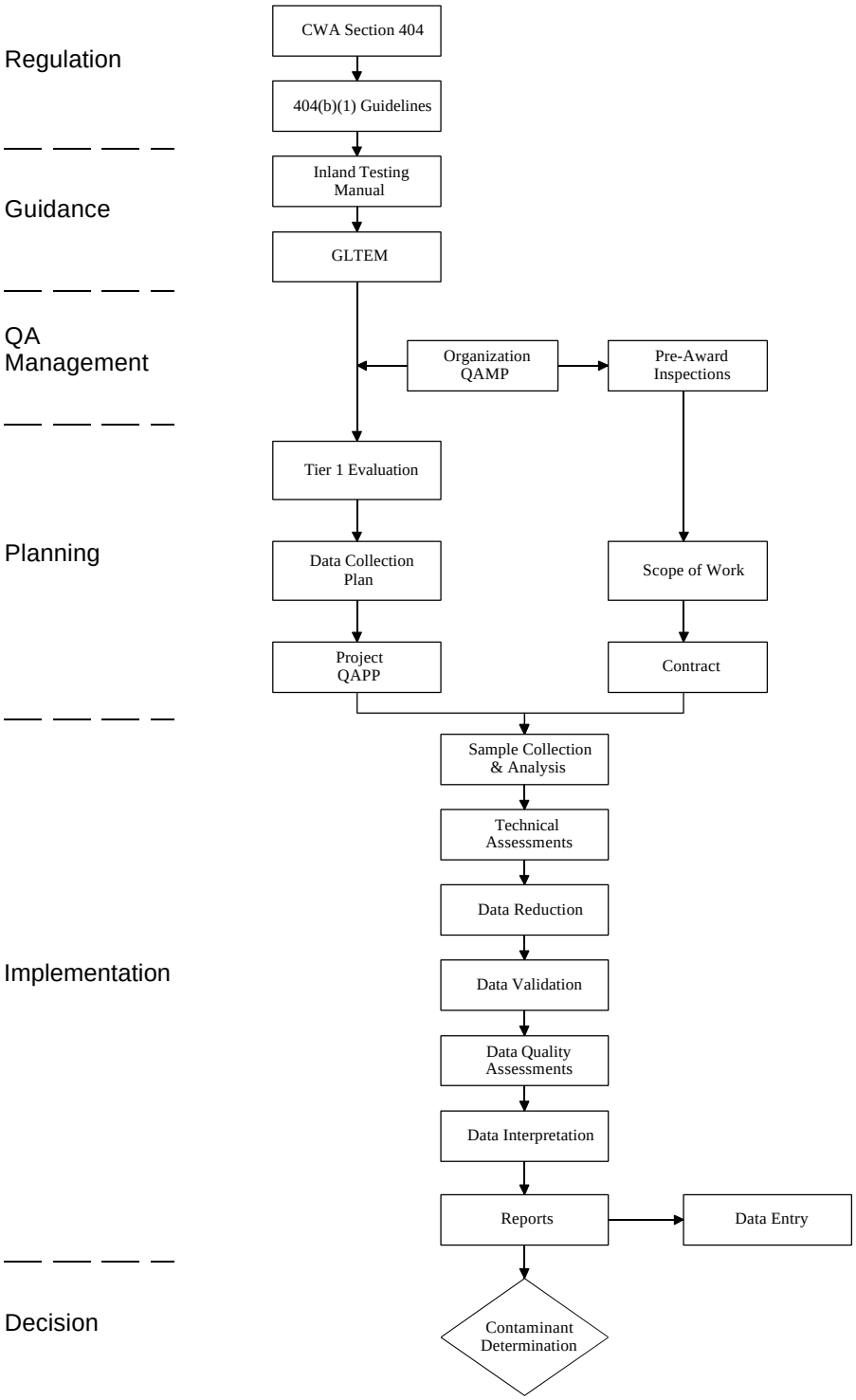

Figure E-1. Overview of Quality Assurance Program for Great Lakes Dredged Material Evaluations

The structure and objectives of the program are described in this section, including:

- relevant quality assurance management documents,
- project coordination,
- project decisions and decision criteria,
- data quality indicators,
- special project needs,
- quality assurance project plans, and
- program and data quality assessments.

3.1 Quality Assurance Management

All organizations involved in collecting data for a 404(b)(1) contaminant determination should have a quality management system. The USACE North Central Division (NCD) "Quality Assurance Management Program (QAMP) for Environmental Data Collection" (NCD 1994) describes the fundamental QA requirements for environmental data collection activities conducted by or on behalf of the USACE districts. This QAMP requires that all districts have a district-specific QAMP and a District Quality Assurance Coordinator.

Applicants for Section 404 permits collecting environmental data should have an established QA management system and a QA Officer. The permittee QA management system should be documented through a plan that describes corporate QA policies and general requirements for all environmental data collection activities.

Each field or laboratory contractor should have an established QA management system and a QA Officer. The contractor QA management system should be documented through a plan that describes corporate QA policies and requirements for all environmental data collection activities as well as standard operating procedures for both QA management and data collection activities. The QA program of subcontractors should be included in the contract and should meet the same requirements expected of the prime contractor.

USACE contractors may be requested to develop contract-specific QA management plans that are presented for USACE review or approval as delineated in the contract bid. Specific recommendations for contractor QA management systems are defined in the USACE QAMPs, and USACE contract guidance documents.

USACE districts, permit applicants and contractors should continually monitor the effectiveness of their QA management through reviews and assessments, as defined in Section 2.8. For contractors, project staff should also review performance to ensure compliance with contractual requirements. Contractors

should review the performance of subcontractors.

3.2 Project Coordination

Coordination of proposed dredged material disposal projects is discussed in various sections of the GLTEM. The purpose of coordination is to solicit input from agencies which will take part in the decision making process prior to any field activities. Coordination should occur during the planning and review of data collection activities. Coordination mechanisms may include scoping meetings, review of planning documents, and review of project reports.

For USACE dredging projects, the responsibility for coordination with other agencies rests with the Project Manager. For Section 404 permit applications involving dredged material discharge, it is strongly recommended that applicants coordinate with the USACE prior to contracting or initiation of field work. The USACE will facilitate coordination of permit evaluations with other agencies.

Several documents produced during a 404(b)(1) evaluation are critical to project coordination. These include the Tier 1 evaluation and the data collection plan. The recommended contents of the Tier 1 evaluation report are discussed in the GLTEM. A data collection plan (DCP) is a document which describes, in detail, the proposed sampling and analysis. The DCP serves as the primary document for project coordination in advance of the proposed sampling and testing. It will also provide much of the information needed for the QAPP and may serve as a scope(s) of work (SOW) for contractors who will implement all or part of the plan.

The DCP should clearly define the goals of the project, define performance criteria for sample design and analytical data quality, establish QA guidelines consistent with project goals, and develop technical strategies to minimize project costs and maintain timelines. The DCP should clearly describe all field and laboratory activities, describe procedures, define performance criteria, and establish QA and QC consistent with the goals in the GLTEM. The plan should discuss organization and responsibilities for implementation and oversight of field and laboratory activities as well as reduction, review, and reporting of results.

The plan should balance the need for an appropriate level of detail with timeliness and cost considerations. Accepted methods and procedures detailed in the GLTEM and appendices can be included by reference. More extensive documentation would be necessary for work to be done by modified/new methods.

Documentation for modified and new methods is discussed in Section 3.5.

Project coordination should continue during implementation of sampling and analysis as problems or changing conditions arise. The relatively short time period for dredged material evaluations will normally limit communication to informal contacts, such as telephone calls and on-site visits. Procurement and contracting personnel should be notified of any contractor problems.

3.3 Project Decisions and Decision Criteria

Dredged material testing and evaluation is ultimately directed toward a single project decision; whether or not the dredged material will have unacceptable contaminant-related impacts on the aquatic environment. The path to this "contaminant determination" involves numerous other decisions in the tiered testing framework. At the end of each of the first three tiers, one of the following conclusions can be made:

- the information available is sufficient for a decision of compliance,
- the information available is sufficient for a decision of non-compliance, or
- the information available is not sufficient for a decision and further testing is necessary at a higher tier.

Testing is conducted in this tiered structure only to the tier at which a decision of compliance or non-compliance can be made. Decisions of compliance can be made independently for each "management unit" of dredged material delineated. Management units are discussed in Sections 2.3 and 2.4 of the GLTEM and Appendix D.

The major decision criteria for dredged material evaluations were promulgated by the USEPA and USACE in the 404(b)(1) Guidelines, published as final in 1986. The water quality standards adopted by States are also decision criteria for a dredged material evaluation. Other decision criteria were established by the USEPA and USACE as part of guidance published in the "Inland Testing Manual" and GLTEM. For some projects, additional decision criteria will be developed by the USACE in consultation with the USEPA during the planning phase.

Most of the decision criteria are relative, based on a comparison of the proposed dredged material with the sediment at the disposal site. The physical and chemical characteristics of dredged material and disposal site sediments, and results of biological effect-based tests with these materials are compared

to make decisions about compliance and the need for further testing. Some of these comparisons are quantitative (statistical significance) while others are more qualitative (weight of evidence). The disposal site is considered as a single unit (i.e., one value with a known uncertainty for each parameter) and serves as the source of comparison for all management units.

Absolute decision criteria for dredged material evaluations have been developed for water column toxicity tests results and compliance with State water quality standards. The following sections discuss the intended use of each type of data collected for the four tiers.

3.3.1 Historical data and records

Historical data and records are compiled during Tier 1 in order to determine if any additional data collection is necessary for a determination of compliance. Sources of these records are discussed in the GLTEM and Appendix C. Historical data can be used as decision points in Tier 1 to determine the applicability of the exclusions from testing. In one decision point, historic data is used to determine the absence of contamination in the proposed dredged material. In the other decision point, historic data on the physical, chemical and biological characteristics of sediments from adjacent dredging and disposal sites are compared, as follows:

> IF the physical, chemical and biological characteristics of sediments at the proposed dredging and disposal sites are not substantially different and the geochemical environments at the sites are similar, THEN no further testing should be necessary to make a contaminant determination.

Tier 1 decision points are based on a "weight-of-evidence" approach. Historical datasets can also be used as a decision point in Tier 1 where there is adequate information of previous Tier 2 and/or 3 testing to make a determination.

3.3.2 Field measurements

Field observations and measurements are conducted as part of every sampling event, and may be used in dredged material evaluations for a number of purposes, including:

- establish positions of sampling locations,
- assess disposal site or management unit homogeneity,
- characterize site conditions at the time of sampling,
- identify and/or characterize the samples collected, and
- as input parameters for the mixing model.

Field observations and measurements may be used as decision points in Tier 1 evaluations, in conjunction with historic information.

3.3.3 Physical characterization of sediment

Physical characteristics of sediments are used as a decision point in Tier 1 to determine the applicability of exclusions from testing, as discussed above. Sediment physical measurements are also used in conjunction with other information as follows:

- indicators of sediment heterogeneity for use in sampling design,
- identify appropriate control and disposal site sediments,
- input parameters to the mixing model, and
- adjust and/or evaluate contaminant concentrations measured (e.g., adjust wet weight to dry weight concentrations).

3.3.4 Chemical analysis of sediment

Sediment bulk chemical concentrations can be used as a decision point in Tier 1 to determine the applicability of exclusions from testing, as discussed above. In some cases, new physical and chemical data are collected to verify a decision in Tier 1.

Sediment chemical data is also used as part of two decision points in Tier 2. The data is used as input to the mixing model to determine the **potential** for exceeding State water quality standards:

> IF the calculated water column concentrations of all contaminants of concern at the edge of the mixing zone are within applicable State water quality standards and IF no interactive effects are suspected, THEN the proposed dredged material discharge should not adversely affect the water column.
>
> IF the calculated water column concentrations exceed applicable State water quality standards, THEN the model must be re-run using elutriate concentrations.

Chemical concentrations of bioaccumulative contaminants of concern and total organic carbon (TOC) in the dredged material and disposal site sediment are used as input to the TBP model to determine the **potential** for benthic bioaccumulation in the dredged material, relative to the disposal site:

IF the calculated TBP from the proposed dredged material is not greater than that of the disposal site material, THEN benthic bioaccumulation testing for the specific contaminant is not required.

IF the calculated TBP from the proposed dredged material exceeds that of the disposal site material, THEN a benthic bioaccumulation test is required.

The TBP decision point is limited to non-polar organic contaminants and sediments having TOC greater than 0.4 percent.

Sediment bulk chemical data is also used in conjunction with other information as follows:

- to develop or modify the contaminants of concern list,
- to indicate distribution of sediment contaminants for the delineation of management units for subsequent sampling, and
- identify appropriate control and disposal site sediments.

3.3.5 Chemical analysis of water and elutriate

The results of the standard elutriate tests serve as the input to the mixing model for determining if the dredged material discharge will exceed applicable State water quality standards, after allowing for mixing:

IF the calculated water column concentrations of all contaminants of concern at the edge of the mixing zone are within applicable State water quality standards and IF no interactive effects are suspected, THEN the proposed dredged material discharge should not adversely affect the water column.

IF the calculated water column concentrations exceed applicable State water quality standards outside the mixing zone, THEN the discharge would not be in compliance UNLESS the State waived 401 certification.

IF State water quality standards do not exist for all contaminants of concern, or IF interactive effects are suspected among parameters, THEN water column impacts must be evaluated by the bioassays in Tier 3.

Chemical data for elutriates can also be used to identify potential non-contaminant impacts to biological test conditions (i.e., ammonia toxicity). Elutriates prepared for biological testing are routinely monitored to assure that test conditions are maintained within acceptable limits.

3.3.6 Water column toxicity tests

If a contaminant determination is not reached in Tier 1, and there are potential interactive effects of dredged material contaminants, the impacts of the dredged material discharge on the water column will have to be assessed in Tier 3. Appendix G describes protocols for water column toxicity tests for three organisms and two exposure periods. The GLTEM recommends that only one test organism need be utilized for a Tier 3 assessment, either *Daphnia magna* or *Ceriodaphnia sp.* and that only the acute (short-term) exposures and survival end-point be used at this time.

The GLTEM suggests that the water column toxicity tests be first run only with the 100-percent elutriate, and interpreted as follows:

> IF the survival in the 100-percent elutriate treatment is not statistically different from the dilution water using a two-sample t-test, THEN the elutriate is predicted not to be acutely toxic to water column organisms.
>
> IF the survival in the 100-percent elutriate treatment is greater than 50 percent, AND the calculated elutriate concentration at the edge of the mixing zone is less than 0.01 of the 100-percent elutriate, the dredged material discharge is predicted not to be acutely toxic to water column organisms outside the mixing zone.

If the survival in the 100-percent elutriate treatment is less than 50 percent, the water column tests must be rerun using a dilution series in order to calculate the LC_{50}. The mixing model is then used to calculate the concentration at the edge of the mixing zone:

> IF the concentration at the edge of the mixing zone is less than 0.01 of the LC_{50}, the dredged material discharge is predicted not to be acutely toxic to water column organisms outside the mixing zone.
>
> IF the concentration at the edge of the mixing zone is greater than 0.01 of the LC_{50}, the dredged material discharge is not in compliance.

3.3.7 Benthic bioassays

If a contaminant determination is not reached in Tier 1, and there are potential interactive effects of dredged material contaminants, the impacts of the dredged material discharge on benthic organisms will have to be assessed in Tier 3. Appendix G

describes protocols for two benthic organisms; *Chironomus tentans* and *Hyalella azteca*. The GLTEM recommends that both test organisms should be utilized for a Tier 3 assessment, and that survival (both organisms) and growth (*C. tentans* only) end-points be measured.

The results of benthic bioassays with the proposed dredged material are statistically compared to those of the disposal site material. Evaluations are made using Fisher's Least Significant Difference (LSD) when the response of two samples means is being compared. The LSD is usually performed following with analysis of variance (ANOVA). When parametric tests are not appropriate for multiple comparisons because the normality assumption is violated, nonparametric procedures should be employed.

The results for survival and growth are evaluated independently:

IF the mean survival of either test organisms exposed to the proposed dredged material is not less than that with the disposal site material by more than 10-percent (20-percent for *C. tentans*), OR the survival of either test organisms exposed to the proposed dredged material is not statistically less that with the disposal site material, THEN the dredged material should not adversely affect the benthos.

IF the mean survival of either test organisms exposed to the proposed dredged material is less than that with the disposal site material by more than 10-percent (20-percent for *C. tentans*), AND the survival of either test organisms exposed to the proposed dredged material is statistically less that with the disposal site material, THEN the dredged material would have unacceptable adverse impacts on benthos.

IF the mean weight of *C. tentans* exposed to the proposed dredged material is equal to or greater than 0.6 mg/organism, OR is not less than that with the disposal site material by more than 10 percent, OR is not statistically less than that with the disposal site material, THEN the dredged material should not adversely affect the benthos.

IF the mean weight of *C. tentans* exposed to the proposed dredged material is less than 0.6 mg/organism, AND is less than that with the disposal site material by more than 10 percent, AND is statistically less than that with the disposal site material, THEN the dredged material would have unacceptable adverse impacts on benthos.

Unacceptable survival for either test organism or for *C. tentans* growth will produce a negative determination.

3.3.8 Bioaccumulation tests

If a contaminant determination is not reached in Tier 1, and there are bioaccumulative contaminants of concern, and if the results of TBP model analysis in Tier 2 indicates the potential for unacceptable bioaccumulation, the impacts of the dredged material discharge on benthic bioaccumulation will have to be assessed in Tier 3. Appendix G describes a test protocol for benthic bioaccumulation in *Lumbriculus variegatus*.

The concentrations of bioaccumulative contaminants of concern in the tissues of the organisms exposed to the dredged material are compared to those in organisms exposed to the disposal site material:

> IF the contaminant concentrations in the tissue exposed to the dredged material does not statistically exceed that of tissue exposed to disposal site material, THEN the dredged material should not have unacceptable bioaccumulation impacts.
>
> IF the contaminant concentrations in the tissue exposed to the dredged material is statistically greater than that of tissue exposed to disposal site material, THEN the dredged material would have unacceptable adverse impacts on benthos.

3.3.9 Tier 4 site specific testing

Testing procedures and decision criteria for Tier 4 will be developed jointly by the USACE and USEPA for project specific applications. In most cases, the decision criteria will be similar to those used in Tier 3, based on a comparison of biological effects of organisms exposed to dredged material and disposal site material or the responses of organisms exposed to dredged material elutriate preparations.

3.4 Data Quality Indicators

Data quality indicators (DQIs) are measurable attributes that are used to assess if the necessary quality of data was attained. Indicators include sensitivity, accuracy, precision, completeness, representativeness and comparability. Acceptance limits for the DQIs for each measurement represent a minimum standard of performance required of project design, equipment, or methods.

Acceptance criteria for project DQIs should be specified in project planning documents as well as associated contractual

documents. When performance does not meet these acceptance criteria, corrective actions should be initiated immediately. Corrective action should also be initiated when seven or more results within acceptance criteria form a trend. If acceptable performance cannot be obtained, the samples and/or measurements may be qualified or invalidated during internal verification or external validation. Only valid data can be interpreted and assessed prior to making decisions. A detailed discussion of data quality indicators is provided in Attachment E-1.

For the GLTEM, the minimum acceptance limits for DQIs correspond to the QC acceptance criteria stated in the protocols in Appendices F and G. These protocols are summarized in table E-2. Tables E-3 through E-6 summarize the sensitivity or method detection limit, precision, and accuracy for the measurements in Appendices D, F and G. These DQIs should be suitable for most dredged material evaluations. However, DQIs may have to be modified or established for specific measurement needs. For project measurements which have more than one intended use, the stricter DQI requirements should generally apply.

Table E-2 Standardized Methods in Appendices F and G

Parameter	Water/ Elutriate	Sediment
Total solids	-	+
Particle size	N/A	+
Total volatile solids	+	+
Specific gravity	-	+
Total dissolved solids	+	-
Total suspended solids	+	-
Ammonia-nitrogen	+	+
Cyanide, Total	+	+
Arsenic, Total	+	+
Cadmium, Total	+	+
Chromium, Total	+	+
Copper, Total	+	+

Table E-2 Standardized Methods in Appendices F and G (continued)

Mercury, Total	+	+
Nickel, Total	+	+
Lead, Total	+	+
Zinc, Total	+	+
Parameter	Water/ Elutriate	Sediment
Total organic carbon	+	+
Total phenols	+	+
Total petroleum hydrocarbons	+	+
Total PCBs and pesticides	+	+
Polynuclear aromatic hydrocarbons	+	+
Ceriodaphnia dubia	+	-
Chironomus tentans	-	+
Daphnia magna	+	-
Hyalella azteca	-	+
Pimephales promelas	+	-
Lumbriculus variegatus	-	+

N/A = not applicable

Guidance for setting DQIs for non-typical measurements is discussed in Section 3.5. Additional DQI guidance is provided in USEPA (1993d) and Sturgis (1990).

3.4.1 Field measurements

General guidance on field measurements associated with sediment sample collection is provided in Appendix D. No specific DQIs have been developed for field measurements associated with Great Lakes dredged material evaluations. USACE districts may establish DQIs for field measurements as part of SOPs for sediment sampling.

Table E-3 Data Quality Indicators for Physical Characterization of Sediment

Measurement	Intended Data Uses	MDL[a]	Precision	Accuracy
Particle size	• determine exclusion from testing • input variable to mixing model • compare dredging and disposal sites • choose control sediment for bioassays	0.001g	RPD ≤10% each fraction	N/A
Specific gravity	• input variable to mixing model • compare dredging and disposal sites	0.001g	≤ 10%	N/A
Total volatile solids (%, dry)	• determine exclusion from testing • input variable to mixing model • compare dredging and disposal sites	0.001g	≤ 10%	N/A
Total solids (%)	• input variable to mixing model • for calculating dry weight results	0.001g	≤ 10%	N/A

[a] method detection limit determined by sensitivity of balance (1 mg)

Legend: N/A=not applicable
RPD=relative percent difference between duplicates

Table E-4 Data Quality Indicators for Physical Characterizations of Water/Elutriate

Measurement	Intended Data Uses	Sensitivity	Precision	Accuracy
Total dissolved solids (mg/l)	• input parameter to mixing model • monitor biological test conditions	0.001g[a]	≤ 10%	N/A
Total suspended solids (mg/l)	• input parameter to mixing model • monitor biological test conditions	0.001g[a]	≤ 10%	N/A
Total volatile solids		0.001g[a]	≤ 10%	N/A
Hardness (mg/l $CaCO_3$)	• adjust chemical elutriate concentrations of Cd, Cu, Cr^{+3}, Pb, Ni, Zn (criteria @ 100 mg/l, std tables and regression equations exist) • monitor biological test conditions			
pH	• adjust chemical elutriate concentrations of ammonia and phenols • monitor biological test conditions			
Dissolved oxygen	• monitor biological test conditions			
Temperature	• monitor biological test conditions			

[a] method detection limit determined by sensitivity of balance (1 mg)

Legend: N/A=not applicable

Table E-5 Data Quality Indicators for Chemical Composition of Sediments

Measurement	Intended Data Uses	MDL(dry weight)	Precision	Accuracy[a]
Ammonia-N	• determine exclusion from further testing • input variable to water quality screening model • compare dredging and disposal sites	0.1 mg/kg	≤ 20%	± 15%
Arsenic (total)	• same as ammonia-N	1 mg/kg	≤ 20%	± 15%
Cadmium (total)	• same as ammonia-N	1 mg/kg	≤ 20%	± 15%
Chromium (total)	• same as ammonia-N	20 mg/kg	≤ 20%	± 15%
Copper (total)	• same as ammonia-N	5 mg/kg	≤ 20%	± 15%
Lead (total)	• same as ammonia-N	10 mg/kg	≤ 20%	± 15%
Nickel (total)	• same as ammonia-N	15 mg/kg	≤ 20%	± 15%
Mercury (total)	• same as ammonia-N	2 μg/kg	≤ 20%	± 15%
Zinc (total)	• same as ammonia-N	30 mg/kg	≤ 20%	± 15%
Total cyanide	• same as ammonia-N	2 mg/kg	≤ 20%	± 15%
Total organic carbon	• same as ammonia-N • input parameter to TBP model	0.1%	≤ 20%	± 15%
Total petroleum hydrocarbons	• same as ammonia-N • indicator parameter for presence of PAHs	5 mg/kg	≤ 20%	± 15%[b]
Total phenols	• same as ammonia-N • input parameter to TBP model	0.1 mg/kg	≤ 20%	± 15%[b]
Total polychlorinated biphenyls	• same as ammonia-N • input parameter to TBP model	10 μg/kg[c] 1 μg/kg	≤ 25%	± 30%[b]
Polynuclear aromatic hydrocarbons	• same as ammonia-N • input parameter to TBP model	50 μg/kg	≤ 25%	± 30%[b]

[a] Accuracy within (±) of known or certified value, whichever is larger.

[b] Lab control sample recommended be developed for accuracy check with acceptance limit of ± 3 standard deviations from mean value.

[c] MDL for pesticides.

Table E-6 Data Quality Indicators for Chemical Composition of Water/Elutriates

Measurement	Intended Data Uses	MDL[a]	Precision	Accuracy
Ammonia-N	• input variable to mixing model • compare to State water quality standard • monitor biological test conditions	30 μg/L	≤ 20%	± 15%
Arsenic (total)	• input variable to mixing model • compare to State water quality standard	75 μg/L[b]	≤ 20%	± 15%[b]
Cadmium (total)	• same as Arsenic	1 μg/L 4 μg/L[c]	≤ 20%	± 15%[b]
Chromium (total)	• same as Arsenic	1 μg/L 7 μg/L[c]	≤ 20%	± 15%[b]
Copper (total)	• same as Arsenic	1 μg/L 6 μg/L[c]	≤ 20%	± 15%[b]
Lead (total)	• same as Arsenic	50 μg/L	≤ 20%	± 15%[b]
Nickel (total)	• same as Arsenic	25 μg/L	≤ 20%	± 15%
Mercury (total)	• same as Arsenic	0.2 μg/L	≤ 20%	± 15%[b]
Zinc (total)	• same as Arsenic	20 μg/L	≤ 20%	± 15%
Total cyanide	• same as Arsenic	5000 μg/L	≤ 20%	± 15%
Total petroleum hydrocarbons	• indicator parameter for PAHs	100 μg/L	≤ 20%	± 15%
Total phenols	• same as Arsenic	50 μg/L	≤ 20%	± 15%
Total polychlorinated biphenyls	• same as Arsenic	.01 μg/L	≤ 25%	± 30%
Polynuclear aromatic hydrocarbons	• same as Arsenic	10 μg/L	≤ 25%	± 30%

[a] Single values shown represent MDL for metal by ICP.
[b] Same limits for both ICP and GFAA.
[c] MDL for ICP, which is acceptable if value is < criteria.
[d] Detection limit for individual congeners.

3.4.2 Sediment sample collection

Field blanks and duplicate samples are commonly used to assess sampling precision and accuracy for many environmental media, but neither are recommended for routine dredged material sampling because of the difficulty in interpreting results and the non-homogeneity of sediments. Representativeness is the primary DQI for sediment sampling, and rationale behind most of the procedures for management unit delineation, collection, and sample homogenization recommended in Appendix D.

3.4.3 Physical and chemical analyses

Minimum acceptable levels of sensitivity, precision and accuracy for physical and chemical analyses of sediment, water, elutriates and tissues as part of Great Lakes dredged material evaluations are listed for each method in Appendix F and summarized on tables E-3 through E-6. The chemical analytical procedures were selected, in part, because of their ability to reliably measure chemical concentrations at background levels representative of the Great Lakes waters and sediments.

3.4.5 Toxicity and bioaccumulation tests

Procedures and acceptance criteria for sensitivity (reference toxicants), precision (minimum number of replicates) and accuracy (organism verification and test conditions) are listed in Appendix G.

3.4.6 Model evaluations

The "Inland Testing Manual" and GLTEM utilize two models to predict water column impacts and bioaccumulation potential. The sensitivity and accuracy of model calculations cannot be evaluated in the traditional sense since the sensitivity of the output to changes in the input(s) will vary with the function of the input variable(s) in the algorithm. The sensitivity of a particular output will depend on the dominant input variable(s) for a project, and has to be evaluated on a parameter-specific basis.

Precision of model outputs should be calculated by using each replicate data point rather than the average of the replicates. A minimum acceptable level of precision for the two models does not exist. However, if a sufficient number of replicates were tested, minimum acceptable levels of precision can be determined using a statistical test for outliers. This is beyond the scope of most dredged material evaluations.

3.5 Special Project Needs and Alternate Procedures

During the planning of a project, it may become evident that modified or new procedures will be required. Reasons for requiring new or modified procedures include:

- sediment sampling procedures recommended in Appendix D are not feasible or will not satisfy project DQOs,
- contaminant of concern list includes parameter(s) for which an approved analytical method is not provided in Appendix F,
- matrix effects have limited the usability of results generated using the approved methods in Appendix F, and
- any Tier 4 testing.

For projects requiring new or modified procedures, additional lead-time will be needed for planning, documentation and coordination. The data quality objective process (discussed in Section 2.4) should be completed to ensure appropriate procedures and associated QA/QC are chosen.

Standard methods are easier to incorporate into a project than method modification or new method development. "Standard methods" are published methods which have been approved by a recognized authority and may generally be incorporated directly into project documents. Modified and new method performance must be evaluated prior to QAPP preparation. Method modification and development typically require special contract-SOWs.

It is important to distinguish method modifications from options stated in the method. Modifications are changes to specific instructions in the method and may affect the validity or quality of results. Options are variations, allowed at the user's discretion, which should not affect the validity of results if appropriate performance is maintained.

Permittees or USACE contractors may propose alternative standard procedures to those in Appendices D, F, and G of the GLTEM. Detailed descriptions of the alternative methods and demonstration of their ability to meet project DQOs should be submitted to the USACE for review and approval prior to their use. The USACE may consult with the USEPA on alternate method acceptance and can dismiss data not obtained by accepted procedures.

3.5.1 Setting decision criteria

The decision criteria for data utilized in Tiers 1, 2, and 3, as discussed in Section 3.3, are not changed for data collected using alternate methods. For Tier 4 evaluations there

are no specific protocols recommended, and project-specific decision criteria will have to be developed for all tests utilized. In most cases, Tier 4 decision criteria will be based on comparisons of results with dredged material and disposal site material.

3.5.2 Selection of methods and setting DQIs

The selection of DQIs and methods are inherently related. Very often, the available method(s) is the determinant for sensitivity/method detection limit, comparability and representativeness as well as to a lesser extent, precision, accuracy, completeness.

Sample collection and handling: The primary DQI considered in selecting sampling equipment and procedures is sample representativeness. Refer to section 4 of Appendix D for guidance in choosing appropriate sample handling equipment and techniques.

Physical and chemical analytical methods: Parameters which are not included in Appendix F should be analyzed using a "standard method", if available. The "Inland Testing Manual", which has a more extensive list of parameters than the GLTEM, should be consulted for method recommendations. For parameters not discussed in the "Inland Testing Manual", methods approved for the Clean Water Act (Federal Register Volume 49, Number 136, October 26, 1984) or the Resource Conservation and Recovery Act (Federal Register Volume 58, Number 167, August 31, 1993) may be appropriate, depending on the constituent and matrix. Other possible method references are USEPA (1979; 1983; 1991b; 1993e; 1993h), Plumb (1981), and APHA/AWWA (1993).

Modifications of "standard procedures" may be needed to achieve a lower MDL, measure a new analyte, remove interferences, and validate a method for a new sample matrix. Lower MDLs can be attained by increasing sample size and concentrating the sample into a smaller volume. Interferences can be physically removed from the sample prior to analysis, or by manipulations during or after analysis. Physical removal of interferences typically requires additional "clean-up" steps and associated QC be performed. A new analyte may be measured in a sediment matrix using a modification of procedures used for water and wastewater analysis if sediment preparation and appropriate clean-up procedures are included.

Biological effects-based tests: Modifications to the toxicity and bioaccumulation tests described in Appendix G and new tests for Tier 4 application should not be pursued without USACE and USEPA coordination. The "Inland Testing Manual" has a

listing of alternate test organisms which may be considered, although not all are appropriate for application to Great Lakes dredged material evaluations. Other possible method references include USEPA (1993i; in prep) and ASTM (1993).

3.5.3 Review and approval of new or alternate methods

Standard operating procedures: Modified standard methods and new methods developed should be documented as an SOP. Guidance for preparing SOPs is provided in Attachment E-2. Protocol format should be similar to those in the Appendices D, F and G. The procedure to be used to validate the method should be described in detail. Criteria for "acceptable method performance" should be included in the procedure. Both the type and amount of data, and the acceptance criteria should be set by reviewing project data quality objectives.

For alternate standard methods not in Appendices D, F, and G, laboratories may prefer to substitute the SOP with a reference to the method manual and procedure number(s) and an addendum page specifying any options listed in the method.

Method verification and validation: Modified and new sampling procedures should be tested prior to collection of samples, if reasonably possible. The verification of performance is not as rigorous as the validation procedure for laboratory tests. Performance of the sampler is typically assessed in terms of percent sample recovery and reproducibility. Bias should be determined by comparing samples collected with two or more different types of samplers.

For modified standard methods, a single laboratory evaluation should be performed which include the following:

1) Identifies the limits of reliable measurement. Two concentrations should be selected, one near the lower and one near the upper end of the response range. Four to ten replicates of each concentration should be analyzed to verify that sensitivity, precision and accuracy do not deteriorate at either extreme.

2) Identifies method precision and accuracy using a single concentration of a standard reference material. Four to ten successive analyses (i.e., a series that yields valid responses by following the method protocol) are typically conducted for each step. The determination of method precision, for example, requires that ten successive independent analyses be conducted on the same sample material. Multistage calculations to determine the required number of analyses might be conducted as more information becomes available on the expected variance. However,

10 analyses will allow the test laboratory to estimate the standard deviation to within 45% of its true value (at a 95% confidence interval). Each value must represent a valid test response and, therefore, includes whatever QC analyses (e.g. blanks, replicates. etc.) are required in the original method protocol to ensure a valid test response.

3) Have performance-based matrix-specific QC data to evaluate data quality parameters such as precision, accuracy, uncertainty, completeness, representativeness, and comparability. This includes, as a minimum:

- MDL or reference toxicant study,
- method blanks or negative control,
- matrix spike or analysis of test materials and associated mean/percent recovery data for at least three representative types of materials,
- standard deviation data from replicate analyses ($n \geq 3$),
- calibration or response range, and
- method interferences and limitations.

Full validation of new methods requires:

1) Evaluating performance during single-laboratory testing.

2) Identification of procedural variables that must be carefully controlled (ruggedness testing).

3) Evaluating method sensitivity by sequential analysis.

4) Evaluating systematic error (bias). Tested materials should include certified reference materials or reference materials, or synthetic samples based upon availability of each material for the specific test.

5) Using performance-based matrix-specific QC data to calculate false positive and false negative rates as a function of concentration and uncertainty as a function of concentration.

6) Multi-laboratory (minimum of 3 labs) confirmation testing.

Review and approval: The results of method verification/validation should be documented and submitted with the proposed SOP to the USACE for review and approval. The USACE will coordinate the review with the USEPA and other experts, as necessary.

3.6 Quality Assurance Project Plans

As stated in Section 2.5, the purpose of Quality Assurance Project Plans (QAPPs) is to document how QA/QC activities are planned, implemented, and assessed during the life cycle of a project. Since 1980, the USEPA has required a QAPP format that follows the 16 essential elements. Use of a standard format promoted consistency between projects and expedited preparation and review of the documents. However, the development and review of a QAPP does represent a significant effort.

QAPPs have not been routinely prepared for dredged material evaluations, and the time and effort required for developing and coordinating traditional QAPPs are beyond the resources of typical dredging projects and would cause unacceptable delays in Section 404 permit decisions. However, the complexity and cost of testing procedures required by the GLTEM necessitate that quality assurance procedures be documented in some form.

3.6.1 Modified QAPP format

A modified QAPP format has been adopted for Great Lakes dredged material evaluations which provides the same information as the traditional 16-sectioned QAPP, but gives project managers flexibility in how and where this information is documented. The project manager always has the option of generating a traditional 16-sectioned QAPP.

The modified QAPP format was developed to minimize the duplication of information by allowing the GLTEM and other project documents containing the relevant information to be cited. Several project documents are developed which may contain the information about the proposed dredging and disposal, data collection implementation, and quality assurance, including:

- Tier 1 evaluation reports,
- data collection plans (DCPs),
- project coordination documents, and
- scopes of work (SOWs) for contracts.

For many projects, the majority of the QAPP can be developed simply by cross-referencing the 16 critical elements with existing project documents. The elements of the modified QAPP and possible information sources are summarized on table E-7. A more detailed discussion of the QAPP contents is provided in Attachment E-3.

3.6.2 Applicability

This modified QAPP format is applicable to the majority of proposed dredged material discharge projects, where the DQOs,

Table E.7 QAPP Element Content and Sources

Element	Description	Contents	Potential Sources
1	Title and signature page	• signatures of project manager, QA coordinators, field and lab managers	• original
2	Table of contents	• self evident	• original
3	Project description	• description of proposed dredging and disposal actions • background information (see Section 3.7 of GLTEM) • objectives of dredged material evaluation • project decisions and decision criteria • sampling plan	• Tier 1 evaluation report • DCP
4	Project organization and responsibility	• organization plan which identifies key personnel and assigns responsibilities for implementation	• QAMP • DCP
5	Sampling and measurement quality objectives	• DQIs	• Appendices D, F & G • DCP or SOW (for modified or new procedures)
6	Sample collection and handling procedures	• sampling equipment and procedures • sample containers • sample handling and storage	• Appendix D • DCP • SOW (contract)
7	Sample documentation, custody and tracking	• sample labeling and documentation • chain-of-custody procedures • bulk sample transfer/distribution	• Appendix D • DCP • SOW (contract)
8	Calibration procedures and frequency	• identify analytical equipment or instruments • describe calibration procedures	• Appendices D, F & G • DCP or SOW (for modified or new procedures)
9	Field and laboratory measurement procedures	• SOPs for analytical methods	• Appendices D, F & G • DCP or SOW (for modified or new procedures)

10	Internal quality control checks	• identify stages where QC checks are made to calculate DQIs • identify all QC samples and checks	• Appendices D, F & G • DCP or SOW (for modified or new procedures)
11	Data reduction, verification, deliverables and data validation and reporting	• describe reduction of raw data to final units • describe verification • describe validation procedures • specify reporting requirements	• Appendices D, F & G • DCP • SOW (contract)
12	Performance audits and systems inspections	• describe pre-award laboratory inspections and criteria • describe internal and external audits • reporting requirements and formats	• QAMP • DCP • SOW (contract)
13	Equipment/instrument maintenance and consumables inspection	• identify equipment or instruments requiring maintenance • describe maintenance protocols • verify availability of critical spare parts • discuss how repairs will be made • discuss how supplies and consumables are inspected and acceptance criteria	• Appendices D, F & G • DCP • SOW (contract)
14	Procedures to assess data usability	• describe procedures to assess data usability for project decision • describe procedures to assess data acceptability for contract payment	• QAMP • DCP • SOW (contract)
15	Corrective action	• list activities potentially requiring corrective action • describe mechanism to implement corrective actions • format for reporting	• Appendices D, F & G • DCP • SOW (contract)
16	Quality assurance reports	• describe QA reports to management	• QAMP

DQIs, and procedures of the GLTEM and appendices are utilized without significant modification. This approach may also be applicable for projects using other "standard methods", if the method SOP contains all of QAPP-required method and QC information.

For projects involving substantial modifications to approved methods, or new methods requiring extensive outside review or compilation of information (i.e., non-typical parameters, site-specific or Tier 4 testing), a traditional 16-sectioned QAPP may be efficacious.

3.7 Data Quality Assessments

A DQA is a quantitative process that focuses on whether the data can be used to make project decisions and, if not, what the use limitations are. DQA applies to all types of validated environmental data, including field measurements and model results. How DQA is performed and by whom, should be specified in each project QAPP.

Validated data should be assessed for compliance with project DQOs. Special emphasis should be placed on how overall DQIs (e.g., sensitivity, precision, accuracy, completeness, representativeness, comparability) were derived from the data. The data assessor should compare the precision and accuracy achieved with that required to verify that the measurement system was in control and met the project objectives. The degree of precision and accuracy serve as an estimate of the uncertainty, and influence the level of confidence with which decisions are made. Audit findings and corrective actions should be reviewed since they may affect the reported error estimations and place limits on the uses of certain sample values.

Data completeness can be assessed for two purposes; compliance with a contract scope of work, and compliance with the amount of data required for decision making. The first assessment is made to determine if the terms of a contract have been fulfilled prior to payment. The completeness of the final valid data set is assessed to determine if sufficient information is available to make a determination with the required degree of confidence.

The data assessor must verify that the field design, sample collection and handling, laboratory subsampling and analysis were performed according to criteria and procedures identified in the QAPP. In addition, each type of measurement should be compared with previous information and correlated with other project data to check the reasonableness and validity of results. Statistical and graphical methods may be used for such comparisons.

One common test is the "outlier test" which verifies that all values of the set statistically "belong". Depending on the importance of the data and project requirements, outliers may be accepted and identified or rejected and selectively removed. If the reason for an outlier can be explained, it can generally be removed from a data set. Outliers removed from a data set must be reported and the reasons for their removal justified. Data may be analyzed with and without outliers.

The DQA should be documented as part of the final report on project data and interpretation.

3.8 Quality Assurance Program Assessments

Performance audits and system inspections of field and laboratory activities should be conducted to verify that work is in accordance with specified requirements. The type and frequency of audits conducted by personnel internal and external to the organization should be specified in project QAPP. These types of audits and inspections may be used by:

- contracting personnel to assess contractor capability and performance prior to contract award,
- project management and QA personnel to evaluate the quality of generated data and monitor the effectiveness of the project QA plan, as designated in the project QAPP, and
- contract personnel to monitor compliance with the organization's QA plan, contract SOWs, or project QAPPs.

Performance audits and system inspections should be conducted by individuals not directly involved in the process. Internal audits should be conducted by management and QA personnel in the organization responsible for performing the work. External audits may be conducted by the USACE or USEPA.

3.8.1 Pre-award laboratory inspections

Because dredged material testing for a project is typically conducted at one time, and because of the limited holding times for sediments, problems with laboratory performance discovered after testing has begun may not be correctable. If laboratory performance is not acceptable, sample collection and analysis may have to be repeated entirely. For these reasons, it is imperative that laboratory qualifications and performance be assessed before analysis is started.

Inspections and audits should be used to assess laboratory capability and performance prior to contract award. USACE regulations require that all laboratories performing work for the USACE be inspected prior to contract award. USACE districts will

also inspect contract laboratories for permit applicants, upon request. USACE guidance on laboratory contracting and inspections is provided in USACE (1988) and Sturgis (1990). USACE district QAMPs may include more specific requirements for laboratory inspections. General guidance on laboratory inspections is also found in ISO/IEC (1990) and USEPA (1991a).

Laboratories should be required to have documented records of performance for all methods to be employed. If the laboratory has proposed to conduct a method it has not previously used, or has insufficient performance records, an initial performance study should be conducted for each method prior to analysis of samples. The initial performance study should be repeated any time there is a major change in equipment or in the method.

For analytical procedures, the initial performance study typically consists of assessing precision and accuracy for 4-7 replicates for samples spiked at 10x the MDL. The procedure should be written in the SOP along with initial acceptance criteria and triggers for repeating the study.

For toxicity tests, intralaboratory precision of the range for the test should be determined by performing five or more tests with different batches of test organisms, using the same reference toxicant, at the same concentrations, with the same test conditions, and same data analysis methods. A reference toxicant concentration series (0.5 or higher) should be selected that will consistently provide partial mortalities at two or more concentration of the test chemical.

For biological evaluations, the laboratory should also demonstrate its competence by conducting five control exposures. It is recommended that these five exposures be conducted concurrently with five reference tests. For whole sediment tests, laboratories should also demonstrate their personnel are able to recover an average of at least 90% of the organisms from whole sediment.

Blind performance samples (discussed below) should be used to evaluate laboratory performance prior to contract award, or at least prior to initiation of project testing, when there is still an opportunity to correct problems.

3.8.2 Project-specific assessments

Project-specific audits and inspections should be performed at the onset of field activities with periodic follow-up inspections to correct any deficiencies previously observed and to verify that QA procedures are maintained throughout the process. The focus of these audits and inspections is to evaluate

the degree of conformance of activities with the project QAPP and contract SOWs. Any problems encountered should be discussed with the project manager and conveyed to contracting personnel.

Performance audits: Audit samples (also known as blind samples) should be representative of samples to be analyzed under the contract, and should be of a known or calculable value with a 95% confidence interval (preferably a 95% tolerance interval) established using a technically valid analytical procedure(s). The USACE has established an interlaboratory testing program, involving analysis of identical samples by multiple laboratories in order to assess the continuing capability, performance, and progress of each participating laboratory (USACE 1989). If a laboratory has never participated in the program, the results from participation in other audit sample programs may be evaluated as an indicator of performance or other accreditations considered.

Audit samples may be included for analysis with project samples. The QA Coordinator compares the results with the known values and possibly with values from other laboratories. If performance is unsatisfactory, the data from that laboratory should not be accepted until adequate performance has been demonstrated.

Historically, performance evaluation samples for chemical laboratories have been prepared by fully homogenizing and repeatedly testing either contaminated environmental samples or clean samples spiked with certified reference materials or primary standards. Split samples for physical, chemical, and biological laboratories have been prepared from fully homogenized environmental samples. Audit samples for sediments and water can be obtained from commercial suppliers. Audit samples for sediments and water can also be obtained from the U.S. Army Engineer Waterways Experiment Station through the appropriate USACE district.

Split samples: Split samples are project samples which have been split for concurrent analysis by two or more laboratories (see discussion in Attachment E-1). Because of the lack of sample homogeneity, field-split samples are not generally recommended for sediments. Sediment samples which have been homogenized in the laboratory are more suitable for split sample analysis.

The contractor is typically responsible for splitting and sending samples to the USACE or referee laboratory. The contractor and referee laboratories transmit results to the QA Coordinator of the contracting organization, who analyzes these results and verifies that they are within the predetermined

acceptable range using paired T-tests or scatter plots of the two laboratories results.

If performance is unacceptable, the laboratory should repeat the split sample analysis as part of the next sampling event. If performance is unacceptable on the second split field sample analysis, the laboratory should evaluate instrument and QC procedures, make necessary changes, and repeat the split field sample analysis as part of the next sampling event. If performance is unacceptable on the third split field sample analysis, this non-performance may be considered as a contributory cause for termination for default of the contract. The laboratory typically bears the cost of non-acceptable performance.

Laboratory inspections: Laboratory inspections may be necessary after contract award and during project implementation to assure compliance with requirements specified in the SOW and verify implementation and effectiveness of the corrective actions suggested in previous audits. For indefinite delivery (open-end) contracts, laboratory inspections should be performed at least every two years after award to monitor continued adherence to requirements of the contract. Unresolved inspection deficiencies may be considered as a contributory cause for termination by default of the contract.

Field inspections: A representative of the contracting organization should be present during all field sampling activities to assure compliance with the SOW and QAPP.

Assessment reports: Audit and inspection reports should include the date of the evaluation, information reviewed, person performing the evaluation, findings and problems, and corrective actions recommended to resolve problems. Specific examples of non-compliance or nonconformity should be documented in the report as well as possible reasons for such deficiencies. These reports should be submitted to the project manager immediately following any internal or external on-site inspection or upon receipt of the results of any performance evaluation audits.

3.8.3 Data validation

Validation is an audit of data quality (ADQ) that determines if the data is of known quality, defensible, free of transcription errors, and complete. Validation applies to all types of environmental data, and the procedures and persons responsible for validation should be specified in the QAPP according to the organization's QAMP and GLTEM recommendations.

For Great Lakes dredged material evaluations, a minimum of

10% of environmental data or one sample per batch, whichever is greater, should be validated. General guidance on data validation procedures is provided in Attachment E-4. When problems are found during validation of a data set, the frequency should be increased. The recommended frequency for new measurements and methods, critical parameters, and difficult analyses is 25%.

Validation should be performed by an independent reviewer (i.e., external to the organization that collected or analyzed the samples) using approved, method-specific SOPs. USACE district QA Coordinators will validate data collected by their contractors and data provided by permit applicants using the guidance provided in Attachment E-4 and SOPs developed in district QAMPs.

3.8.4 Corrective action

Corrective action may be required for two classes of problems; procedural and non-compliance. Procedural problems include equipment failures, breaks in custody, and documentation errors. Nonconformance with the established QA procedures in the QAPP or DCP should be identified and corrected in accordance with procedures in the QAPP and associated SOPs. Noncompliance problems include unapproved changes in sample design, data anomalies, and audit failures. A formal corrective action program should be determined and implemented when a noncompliance problem is identified.

The need for corrective action is identified by technical personnel who perform the daily activities. If the problem persists or cannot be resolved, the matter is referred to management and QA personnel for further investigation. Technical staff should not initiate corrective action without prior approval through the proper channels. Management should approve the change in writing or verbally prior to implementation, if feasible, through the same channels. Management is responsible for ensuring that corrective action are initiated by:

- evaluating all reported nonconformances,
- controlling additional work on nonconforming items,
- determining disposition or action to be taken,
- maintaining a log of nonconformances,
- reviewing nonconformance reports and corrective actions, and
- ensuring nonconformance reports and corrective action memos are included in the project file.

If corrective actions do not correct the problem, the manager should stop work until successful corrective action can be taken.

Corrective action for field sampling may include:

- recollecting the sample,
- sampling at a different location, or
- using a different sampling device/procedure,

Corrective action for field measurements may include:

- repeat the measurement to verify the error,
- check for proper adjustment for ambient conditions,
- check batteries,
- check calibration, and
- replace the instrument or measurement device.

Laboratory corrective action is dependent on the type of analysis and the event. Laboratory personnel are alerted that corrective actions may be necessary if:

- samples are received in improper/leaking containers without proper preservation or documentation,
- quality control data are outside the warning or acceptable windows for precision and accuracy,
- blanks contain target analytes or negative controls have responses above acceptable levels,
- undesirable trends are detected in spike recoveries or positive controls, or precision between replicates,
- there are unusual changes in method detection limits or organism sensitivity,
- performance and/or system deficiencies are detected by the QA personnel during internal or external audits, or
- inquiries concerning data quality are received.

Corrective actions for data management may be necessary during data review and data validation, such as:

- obtaining missing information or recovering lost data,
- recalculate data, or
- correcting transcription errors on forms, reports, and databases.

After assessing the data, the project manager may decide to repeat sample collection and/or analyses based on the extent of the deficiencies and their importance in the overall context of the project. Issues which may trigger additional work are:

- insufficient or nonrepresentative samples,
- samples lost due to breakage, loss of integrity (e.g., lack of preservation, exceed holding time) or insufficient volume for testing, or
- method not "in control", producing invalid results.

Nonconformances and corrective actions should be documented in field and laboratory log books. Changes may be requested verbally or by change request forms that are signed by the initiators and management. Nonconformance reports and corrective action memos should be prepared by field or laboratory management, and describe the nonconformance or noncompliance and its significance, recommended solution(s), results of corrective actions, and alternative corrective action (if necessary). Reports and memos should be submitted directly to the project manager. Nonconformance and corrective actions records should be sent with project results to the data validator.

4. REFERENCES

American Public Health Association (APHA), American Water Works Association (AWWA), Water Pollution Control Federation (WPCA). 1993. Standard methods for the analysis of water and wastewater, 18th edition, APHA/AWWA/WPCF, Washington, DC.

American Society of Testing Materials (ASTM). 1993. Annual Book of ASTM Standards, Volume 11.04, ASTM, Philadelphia, PA.

International Standards Organization (ISO)/ (IEC). 1990. "General Requirements for the Competence of Calibration and Testing Laboratories", ISO/IEC Guide 25, Geneva, Switzerland.

ISO/IEC Guide 38 "General Requirements for the Acceptance of Testing Laboratories".

Karn, R.A. and A. B. Strong. 1989. "Quality assurance guidelines for organic analysis," Technical Report EL-89-18, Water Quality Research Program, U.S. Army Engineer Waterways Experiment Station, Vicksburg, MS.

Moore, D.W., Dillion T.M., Word, J.Q., and Ward, J.A. 1994. "Quality assurance/quality control (QA/QC) guidance for laboratory dredged material bioassays; Results of QA/QC workshop held May 26-27, 1993, in Seattle, Washington," Miscellaneous Paper D-94- , U.S. Army Engineer Waterways Experiment Station, Vicksburg, MS.

National Institute of Standards and Technology (NIST). 1992. "Use of NIST SRMs for decisions on performance of analytical chemical methods and laboratories," Special Publication 829, NIST, Gaithersburg, MD.

NIST. 1993. "Handbook for SRM Users," Special Publication 260-100, NIST, Gaithersburg, MD.

North Central Division (NCD). 1994. "Quality assurance management program (QAMP) for environmental data collection," NCD Regulation NCDR 1110-2-27, U.S. Army Engineer Division, North Central, Chicago, IL.

Plumb, R.H., Jr. (editor). 1981. "Procedures for the handling and chemical analysis of sediments and water samples," Technical Report EPA/ACE-81-1, prepared by State University College at Buffalo, Great Lakes Laboratory, Buffalo, NY for U.S. Environmental Protection Agency and U.S. Army Engineer Waterways Experiment Station, Vicksburg, MS.

Sturgis, T.C. 1990. "Guidance for contracting biological and chemical evaluations of dredged material," DOTS Technical Report D-90-10, U.S. Army Engineer Waterways Experiment Station, Vicksburg, MS.

USACE. 1970. "Laboratory soils testing," Engineer Manual EM 1110-2-1906, Department of the Army, Headquarters, Office of the Chief of Engineers, Washington, DC.

USACE. 1974. "Laboratory investigations and material testing," Engineer Regulation ER 1110-1-8100, Department of the Army, Headquarters, Office of the Chief of Engineers, Washington, DC.

USACE. 1976. "Water quality data collection, interpretation and application activities," Engineer Regulation ER 1130-2-415, Department of the Army, Headquarters, Office of the Chief of Engineers, Washington, DC.

USACE. 1979. "USACE work for others; Laboratory investigations and material testing," Engineer Regulation ER 1140-1-210, Department of the Army, Headquarters, Office of the Chief of Engineers, Washington, DC.

USACE. 1980. "Quality control of water quality field sampling activities," Engineer Technical Letter ETL 1110-2-252, Department of the Army, Headquarters, Office of the Chief of Engineers, Washington, DC.

USACE. 1986a. "Contracting guidelines for water quality and other chemical analyses," Engineer Technical Letter ETL 1110-2-298, Department of the Army, Headquarters, Office of the Chief of Engineers, Washington, DC.

USACE. 1986b. "Quality assurance of laboratory testing procedures," Engineer Regulation ER 1110-1-261, Department of the Army, Headquarters, Office of the Chief of Engineers, Washington, DC.

USACE. 1987. "Safety and Health Requirements Manual," Engineer Manual EM 385-1-1, Department of the Army, Headquarters, Office of the Chief of Engineers, Washington, DC.

USACE. 1988. "Water and wastewater laboratory inspections," Engineer Technical Letter ETL 1110-2-309, Department of the Army, Headquarters, Office of the Chief of Engineers, Washington, DC.

USACE. 1989. "Interlaboratory testing program for chemical analyses," Engineer Regulation ER 1110-1-1401, Department of the Army, Headquarters, Office of the Chief of Engineers, Washington, DC.

USEPA. 1979. "Methods manual for bottom sediment sample collection," EPA 905/4-85-004, Central Regional Laboratory, Chicago, IL.

USEPA. 1982. "Handbook for sampling and sample preservation of water and wastewater," EPA-600/4-82-029, Environmental Systems and Monitoring Laboratory, Cincinnati, OH.

USEPA. 1983. "Methods for the chemical analysis of water and wastes," EPA-600/4-79-020, Environmental Systems Monitoring Laboratory, Cincinnati, OH.

USEPA. 1987. "Quality assurance and quality control (QA/QC) for 301(h) monitoring programs; Guidance on field and laboratory methods," EPA 430/9-86/004, Marine Operations Division, Washington, DC.

USEPA. 1991a. "Manual for the evaluation of laboratories performing aquatic toxicity tests," EPA/600/4-90/031, Environmental Monitoring Systems Laboratory, Cincinnati, OH.

USEPA. 1991b. "Methods for the determination of metals in environmental samples," EPA/600-4-91/010, Office of Research and Development, Washington, DC.

USEPA. 1991c. "Preparation aids for the development of category II quality assurance project plans," EPA/600/8-91/004, Office of Research and Development, Risk Reduction and Engineering Laboratory, Cincinnati, OH.

USEPA. 1993a. "Content requirements for quality assurance project plans, Revision 4," R5-QAS-93-001, Region 5, Quality Assurance Section, Chicago, IL.

USEPA. 1993b. "EPA requirements for quality management plans," EPA QA/R-2, Quality Assurance Management Staff, Washington, DC.

USEPA. 1993c. "EPA requirements for quality assurance project plans for environment data operations," EPA QA/R-5, Draft, Quality Assurance Management Staff, Washington, DC.

USEPA. 1993d. "Guidance for planning for data collection in support of environmental decision-making using the data quality objectives process," EPA QA/G-4, Quality Assurance Management Staff, Washington, DC.

USEPA. 1993e. "Methods for the determination of inorganic substances in environmental samples," EPA/600-R-93/100, Office of Research and Development, Washington, DC.

USEPA. 1993f. "Quality assurance manual for environmental data collection, Region 2, Environmental Services Division, Edison, NJ.

USEPA. 1993g. "Test methods for evaluating solid waste: Physical/chemical methods," SW-846, Third Ed., Including Update 1, Office of Solid Waste and Emergency Response, Washington, DC.

USEPA. 1993h. "Methods for the determination of nonconventional pesticides in municipal and industrial wastewater," Revision I, Volumes I and II, EPA-821-R-93-010-A/B, August 1993.

USEPA. 1993i. "Methods for measuring the acute toxicity of effluents and receiving waters to freshwater and marine organisms," Fourth Edition, C.I. Weber (editor), EPA-600/4-90-027F, Environmental Monitoring and Systems Laboratory, Cincinnati, OH.

USEPA. 1994a. "Guidance for preparing, conducting, and reporting the results of management system reviews," QA/G-3, Quality Assurance Management Staff, Washington, DC.

USEPA. 1994b. "Model quality assurance project plan for water programs (check title), R5-QAS/WD-94-003, Region 5, Environmental Sciences Division and Water Division, Chicago, IL.

USEPA. in prep. "Methods for measuring the toxicity and bioaccumulation of sediment- associated contaminants with freshwater invertebrates," EPA 600/R-94/924, Environmental Research Laboratory, Duluth, MN.

USEPA/USACE. 1998. "Evaluation of dredged material proposed for discharge in waters of the U.S.-Testing manual (Inland Testing Manual)," EPA-823-B-98-004, Office of Water, Washington DC.

ATTACHMENT E-1
Data Quality Indicators

1. Sensitivity and Method Detection Limit (MDL)

Definitions of sensitivity and method detection limit (MDL) are different for analytical procedures which measure concentrations/levels, biological tests which measure effects, and models which simulate processes.

1.1 Field measurements

For reasonably stable field measurement equipment, the MDL may be synonymous with the sensitivity of the equipment. This is typically an inherent quality in equipment design and can be obtained from manufacturer's specifications. Be aware, however, that manufacturer's specifications are set under strictly controlled conditions and may not be achievable under field conditions.

1.2 Physical and chemical analyses

Physical characterizations vary in complexity from simple procedures whose sensitivity is limited by the inherent quality of the equipment (similar to simple field equipment) to methods using instruments for which MDLs are statistically calculated. Each laboratory should determine the MDL at least annually for each sample matrix in each method and for each instrument which performs the analysis at the laboratory. The MDL should be re-determined after major changes in the method or instrument. Most method protocols contain procedures to verify the MDL periodically (e.g. daily, weekly). The actual MDL for a given sample is never determined and may be higher than the laboratory MDL due to interferences in the sample or as a result of diluting heavily contaminated samples so the instrument response is within the linear, calibrated range.

For chemical analytical procedures, sensitivity is the smallest incremental change which can be detected. Method detection limit is the smallest concentration which can be determined with a known degree of confidence. The MDL, a procedure adopted by USEPA, is similar to the Limit of Detection (LOD) used by the American Chemical Society (ACS) but is calculated differently. The MDL should not be confused with an instrument detection limit (IDL) which does not reflect the entire method/protocol.

A second limit commonly associated with the MDL (LOD) is the Minimum Level (ML). The ML, a procedure adopted by USEPA, is

similar to the Limit of Quantification (LOQ) used by the ACS. Historically, USACE conservatively defines the LOQ as 10 times the standard deviation observed for the low-level standard or blank sample which is equivalent to 3.18x the MDL. In practice, the ML (LOQ) equals the lowest calibration point.

Both the MDLs and LOQs are specific to a laboratory. For any given protocol, the MDL and associated LOQs varies with equipment, sample volume processed, and sample matrix and complexity. For 404(b)(1) projects, MDLs should be one-fifth to one-tenth, but no greater than one-third, the appropriate value critical to the decision making process (i.e. the "action level"). The MDL should be the reporting limit (RL). Sample values above the MDL but below the ML/LOQ are considered to be estimated data and should be used as a qualitative indicator of "presence" rather than a "quantitative value".

Because precision and accuracy vary with concentration, some laboratories may prefer to evaluate and set parameter MDLs (LODs) and associated MLs (LOQs) to achieve a uniform level of precision and accuracy for all parameters.

1.3 Toxicity and bioaccumulation tests

The sensitivity of biological evaluations cannot be evaluated in the traditional sense since the test measures a 'net effect' rather than response to any one sample characteristic or set of known components. However, the sensitivity (i.e. dose response) of a species to individual reference toxicants or reference material can be quantified.

Contrary to analytical methods, reference toxicant tests are performed on a routine basis (at least monthly) to monitor the sensitivity of the in-house culture or verify the sensitivity of shipped organisms. The laboratory should calculate acceptable limits and control charts for each reference toxicant and test organism. Controls charts are used to evaluate the cumulative trend of results from a series of samples. Endpoints from five tests are adequate for establishing the control charts. In this technique, a running plot is maintained for the values from successive tests. Control limits ($\pm$2 SD) are recalculated with each successive test result. Outliers, which are values falling outside the upper and lower control limits, and trends of increasing or decreasing sensitivity, are readily identified using control charts. Tests conducted during the time the of the outlier reference toxicant test should be considered as provisional and subject to careful review.

1.4 Model calculations

The sensitivity of model calculations cannot be evaluated in the traditional sense since the sensitivity of the output to changes in the input(s) will vary with the function of the input variable(s) in the algorithm. The sensitivity of a particular output will depend on the dominant input variable(s) for a project, and has to be evaluated on a parameter-specific basis.

2. Accuracy

Accuracy is the degree of agreement of a measurement (or an average of replicate measurements), X, with an accepted reference or true value, T. Accuracy is expressed as the difference between the two values, X-T, or the difference as a percentage of the reference or true value, 100 (X-T)/T, and sometimes expressed as a ratio, X/T. For an unknown sample, it is impossible to determine the true accuracy of the measurement. Therefore, accuracy is assessed through the analysis of negative controls/ blanks and positive controls/knowns, with the assumption that the method was calibrated and "in control" during the measurement.

2.1 Field measurements

The accuracy of simple measurements varies with the type of measurement and equipment. Most instrument manuals will provide an estimate of instrument accuracy, which does not include sampling variability. Accuracy of some field measurements may be impossible to measure because there are no standards to serve as references.

2.2 Sediment sample collection

Sources of sampling bias and imprecision cannot be measured because no standards exist to serve as references. Inappropriate equipment and cross contamination are the two most common sources of error. Potential sampling error can be minimized by controlling sample design and collection protocols. Blank and duplicate samples, which actually are a measure of sampling precision, are used to assess sampling accuracy for some environmental media.

Trip blanks are used to assess the potential for contamination of samples due to contaminant migration during sample shipment and storage. A clean sample is taken from the laboratory to the sampling site and returned to the laboratory unopened. Typically, this type of blank applies only to liquid samples collected for volatile analysis. Trip blanks are collected at a frequency of one per cooler or a minimum of one per 20 samples, whichever is greater.

Field blanks (equipment rinsates) are analyzed to check for procedural contamination at the facility which may cause sample contamination. Field blanks consist of a pouring analyte-free water over decontaminated sampling equipment as a check that the decontamination procedures has been adequately carried out and that there is no cross-contamination of samples occurring due to the equipment itself.

Analysis of field blanks is performed for all analytes of interest, but is typically required only when aqueous samples are being collected. Field blanks are not required for solid samples because it is difficult to interpret results and the associated QC costs for analysis of a different sampling matrix (water) can be prohibitive. The need for field blanks may be avoided by using the sample container as the sampling device, and pre-rinsing the container with the sample prior to sample collection.

One field blank should be collected for each type of equipment used each day field decontamination is performed, but are required only for liquid matrices. The rinse must be performed sequentially on all pieces of equipment used in the sampling protocol. The field blank should be collected at the beginning of the day prior to the sampling event and that blank must accompany those samples which were taken that day, at a minimum frequency of one for every ten or fewer investigative samples. This is a necessary procedure so that the blank will be associated with the proper samples during data validation.

For trip or field blanks to be acceptable for use with the accompanying samples, the concentration in the blank of any analyte of concern must, typically, be no higher than the highest of either:

- the method detection limit,
- 5% of the action level for that analyte, or
- 5% of the measured concentration in the sample.

Blank values are never subtracted from sample results, but are reported separately.

2.3 Physical and chemical analyses

Accuracy for laboratory measurements is typically assessed by analyzing laboratory blanks and known or blind reference materials and, for organic analyses, performing matrix spikes on selected samples and adding surrogates for each sample. However before accuracy for any sample set can be assessed using blank, spike, surrogate and reference results, equipment calibrations must be performed and accomplished within the established limits to define the accuracy of the equipment. In addition, test-

specific performance checks monitor test conditions during analysis of the samples.

Calibration: Calibration may be defined as a comparison of a measurement standard or instrument with known accuracy with other standard or instrument to eliminate deviations by adjustment. Calibration accuracy is critically dependent on the purity and reliability of the standard; standards should be traceable to a national standard. Standards may be prepared in the laboratory from neat materials or purchased as a pre-mixed concentrate.

Calibration must be performed under the same instrumental and chemical conditions as those that will exist during the measurement process. Initially, a minimum of three different concentrations of calibration standards should be measured, preferably at least five. The concentrations of the calibration standards must bracket the expected concentration of the analyte in the samples. Where possible, the calibration curve should be generated by suitable regression analysis of the net signal for the concentration. No data should be reported beyond the range of calibration.

For organic analysis, calibration standards may be external or internal. External standards are typically the target analyte being detected and are analyzed separate from environmental samples. Internal standards are compounds which simulates the analyte of interest (e.g. deuterated isotope) that are added to each QC and environmental sample analyzed. The ratio of internal standard response to the analyte response at the same concentration is called the response factor. The response factor must be relatively constant over the calibration range if it is to be used to calculate analyte concentrations.

Another technique, typically used for metal analysis, is the method of standard addition where successive, increasing known amounts of analytes are added to the sample or aliquots of it. It is essential to shown either the spiked chemicals equilibrate with the corresponding endogenous ones, or that the recovery of the spiked chemicals is the same as the recovery of the contaminant from samples (within experimental error) over the full range of concentration levels to be analyzed.

The frequency of calibration and calibration checks depends on the type of calibration (e.g. internal or external), accuracy requirements, stability of the instrument, sample load for the laboratory. External calibrations may be performed daily, weekly, or even monthly. If external calibration is not performed daily, a minimum of two calibration checks (at the beginning and end of the day) should be made. Unstable systems

may require additional checks after every 10th sample.

Test-specific performance checks: Additional instrument and method performance checks are specific to the equipment and method. Instrument and method performance check procedures, frequency, acceptance criteria and corrective actions may be found in instrument manuals and the method protocol.

Method blanks: The method blank is used to document contamination resulting from the analytical protocol. A method blank is a matrix to which all reagents and preservatives are added in the same volumes or proportions used in sample processing. The method blank must be carried through the complete preparation and analytical protocol.

The minimum frequency of method blanks is one per batch of samples processed within a work shift. If more than 20 samples are included in a batch, analyze one for every 20 samples. This frequency should be increased to a minimum of 10% for new parameters and methods. The method blank is typically acceptable if the concentration of any analyte of concern in the matrix is no higher than the highest of either:

- the method detection limit,
- 5% of the action level for that analyte, or
- 5% of the measured concentration in the sample.

Blank values are never subtracted from sample results, but are reported separately.

Matrix spike: A matrix spike is an aliquot of sample (blanks do not require separate matrix spike or duplicate analyses) spiked with a known concentration of target analytes. The spiking occurs prior to sample preparation and analysis. The added concentration should not be less than the background concentration of the sample selected. Ideally, the fortified analyte concentrations should be 10 times the MDL or the action level, whichever is less. A matrix spike is used to document the bias of a method in a given sample matrix.

Matrix spikes should be analyzed at a minimum frequency of one per 20 samples or one per sample batch, whichever frequency is greater. This frequency should be increased to a minimum of 10% for new parameters and methods.

Warning and control limits should be established using the mean value from a minimum of 20 to 30 analyses. The warning limit should be $\pm$ 2 standard deviations of the mean and the control limit should be $\pm$ 3 standard deviations of the mean. After each five to ten new measurements (i.e. daily), new limits

should be calculated using only the most recent 20 to 30 data points. These limits should never exceed those determined during the initial performance study. When measurements fall outside established control limits, that method is judged out-of-control and the source of the problem should be identified and resolved before continuing.

Surrogates: For organic chemical analyses, surrogates provide information about the effectiveness of the method to recover and detect the analyte. A surrogate must be similar to the target analyte(s) in chemical composition and method behavior, but should not be found in environmental samples. The surrogates are added to every sample aliquot, calibration standard, and blank in known amounts before extraction and are measured with the same procedures used to measure other sample components.

The purpose of the surrogate analyte is to monitor method performance with each sample. The recovery of the surrogates in each sample and blank should be evaluated with respect to laboratory control limits (established using a procedure similar to that used for matrix spikes) and continuously tracked. Minimum percent recoveries for each analyte is typically 70-130%.

Reference samples: The Internal Standards Organization (ISO) defines two types of reference samples: reference materials and certified reference materials.

A reference material (RM), not to be confused with the disposal site material used in dredged material evaluations, is a material or substance with one or more properties which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials (ISO 1989). It is important to note that a given RM cannot be used for more than one purpose. Separate RMs must be obtained from different sources (i.e., vendors or lots of material) for instrument calibration and internal QC. For monitoring instrument accuracy, reference materials should be analyzed at least quarterly as well as with each large batch of samples.

A certified reference material (CRM) is a reference material with one or more property values certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body (ISO 1989). CRMs provide a QC test on the entire analytical process from sample preparation to the final reporting of results. For this reason, CRMs are typically used to document the bias of the analytical process during method validation and to compare performance among laboratories.

CRM values should be obtained through multi-lab (typically $\geq$20 laboratories) analysis using the method(s) specified on the Certificate of Analysis accompanying each sample. CRM values should be calculated using the $\pm$95% tolerance interval (TI) rather than a $\pm$95% confidence interval (CI). The TI estimates the uncertainty for the individual user unlike the CI which is a measure of certification of the participating labs and not the CRM. The TI is typically broader (2-6x) than the corresponding CI. CRM values based on 2 times the standard deviation of the mean are not statistical and should not be used.

Sources of CRMs are listed in USEPA (1994b). When CRMs are not available, materials that have been fully homogenized and repeatedly tested can be used. These materials may be contaminated environmental samples or clean samples spiked with a certified reference materials (or primary standards). Currently, CRMs are not available for physical sediment characterizations, all chemical pollutants in sediment, or for biological effects tests. CRMs issued by the National Institute of Standards and Technology (NIST) are called standard reference materials (SRMs).

Documentation accompanying reference samples should: describe applicable matrices and analytes; state if concentration levels are based on analyses of an entire subsample or analyses of an extraction fraction, and method of testing; describe homogeneity assessment of the final unit; describe minimum sample size for testing; describe how bulk material was processed; give handling and storage instructions, preparation and expiration dates (if applicable), and; list the name, address and phone number of the producer. Additional information on the preparation and application of CRMs (SRMs) can be found in NIST 1992; 1993).

2.4 Toxicity and bioaccumulation tests

Quantitative determination of precision and accuracy is difficult or may be impossible in some cases due, in part, to the many unknown variables which affect organism response. Determining the accuracy using field samples is not possible since the true values are not known. Since there is no acceptable reference material suitable for the determining the accuracy of these tests, their accuracy has not been determined.

Accuracy for biological evaluations can be assessed through the use of negative controls and long-term monitoring of the coefficients of variance among reference toxicants. These results, however, are valid only if organisms are appropriate (e.g. taxonomy verified, proper sex and age) and exhibit good health and normal behavior, and test conditions (e.g., temperature, dissolved oxygen) were maintained within pre-set

acceptance limits throughout the study. Test end point outliers are generally more important than test condition outliers.

Organism verification: Since taxonomic verification requires qualified experts (whose opinions may differ), reference toxicant response should be considered as the primary means of assessing test organism appropriateness. The source of test organisms should be documented as well as the response to reference toxicants. If possible, a subsample of test organisms should be preserved.

For each test, the age of the organisms should be documented. If age cannot be determined, the mean size or biomass at testing time should be recorded. Verification of loading rates via double counting is necessary as an internal QC check. At the end of a test, 10% of all endpoints should be verified by another observer.

Culture and test conditions: Environmental conditions for culturing/acclimation of organisms and during exposures should be monitored and maintained as specified in the test protocol. Parameters measured typically include water quality parameters and environmental conditions which affect organism health, care and handling.

Blanks: Negative controls consist of the water in which the organisms have been raised (elutriate test) or a control sediment (whole sediment test). The organism in the control samples should be required to equal or exceed specific criteria (e.g., 90% survival) indicating normal health and behavior stipulated in the testing protocol.

Laboratory water should be checked annually (more often, if necessary) for trace contaminants. In addition, when appropriate, test-organism food and tissues of test organisms held in culture should also be analyzed periodically for the presence of trace contaminants.

Reference toxicants and materials: The response of a given culture of organisms to a known quantity of reference toxicant or a reference material can be evaluated prior to a study, during a study, and over time. The reference toxicant chosen should have an established interlaboratory and intralaboratory database. Reference toxicants often used for freshwater systems are potassium chloride, copper, and zinc. Currently, there are no commercial reference materials available in the quantity required for biological evaluations.

Control charts are constructed by plotting successive toxicity values for each reference toxicant. The mean and

standard deviation are recalculated with each successive plot until the statistics stabilize. Control charts are used to assess whether test organism sensitivity to a given reference toxicant is within interlaboratory and intralaboratory control limits (±2 standard deviations) established for that reference toxicant. A significant change in response or a stable trend (n=7) requires investigation and possible replacement of the culture.

2.5 Model calculations

Accuracy for model calculations cannot be evaluated in the traditional sense. The verification of a model is a significant undertaking, requiring a substantial database and is not a reasonable burden for individual projects. Project data should be evaluated to confirm the chosen input values and assumptions were appropriate. The accuracy of input values should reflect the sensitivity of the model to specific parameters.

3. Precision

Precision is defined as the degree of mutual agreement among independent, similar, or repeated measurements. Various measures of precision exist depending upon the "prescribed similar conditions". Typically, precision is assessed through the use of replicate samples or measurements, and determining the statistical relationship among the results compared to the mean. For triplicate samples or measurements, the percent relative standard deviation (%RSD) is calculated.

3.1 Field measurements

Precision of field measurements is assessed by collecting replicate readings on a sample or standard at the frequency stated in the method. At a minimum, precision should be checked at the beginning and end of the day. Instrument calibration must be valid. Precision should be within the variance indicated in the instrument manual.

3.2 Sediment sample collection

Field duplicate: Field duplicates are collected to demonstrate the reproducibility of sampling technique in homogeneous material, or the degree of environmental heterogeneity. Independent samples are collected as close as possible to the same point in space and time using identical procedures. The two separate samples should be stored in separate containers and analyzed independently. These field QC samples must be treated as regular investigative samples concerning sample volume, containers and preservation.

Split samples: Split samples are aliquots of sample taken from the same container and analyzed independently. These are usually taken after homogenization and are used to document intralaboratory precision (in this case, also known as laboratory duplicates) or interlaboratory accuracy. Samples collected for analysis of volatiles cannot be splits, but must be taken as co-located grab samples. Split sample sets should include field duplicate samples as well as appropriate field blanks.

Because of the heterogeneity of sediments (*in situ*) and the inability to adequately homogenize samples in the field, field duplicates and split samples are not considered reliable indicators of precision in sediment sample collection. Sediment samples homogenized in the laboratory may be suitable for preparing split samples to assess interlaboratory accuracy. However, these would not provide information about sampling precision.

3.3 Physical and chemical analyses

Precision for laboratory measurements is usually assessed by analysis of laboratory duplicates or MS/MSD.

Laboratory duplicates: A laboratory duplicate is an intralaboratory split sample used to document the precision of a method in a given sample matrix. Laboratory duplicates are typically performed for analytes which are naturally occurring and/or frequently found in samples. Results document the precision of a method for a given sample matrix. Duplicates should agree within established laboratory control limits for similar matrices (typically $\leq$10-20%).

Matrix spike duplicates: A matrix spike duplicate is an intralaboratory split sample which is used to document the precision of a method for a given sample matrix. Matrix spike duplicates are typically performed for analytes which are not naturally occurring and/or not frequently found in sample. The intralaboratory split samples are spiked with identical concentrations of target analytes. The spiking occurs prior to sample preparation and analysis. Results document the precision of a method for a given sample matrix. Duplicates should agree within established laboratory control limits for similar matrices (typically $\leq$20-30%).

While both inorganic and organic analyses use matrix spikes, only the organic analyses requires additional sample volume. For this reason, sample and analysis tables list matrix spikes as investigative samples for organic analyses.

3.4 Toxicity and bioaccumulation tests

Biological evaluations are always performed in replicate, typically 3 to 5 with a minimum of 10 organisms per replicate. Precision is not only calculated, but is fundamental to interpretation of results. A measure of precision can be calculated using the mean and relative standard deviation (percent coefficient of variation = standard deviation/mean x 100) of the calculated endpoints from the replicated endpoints of a test. However, precision reported as the CV should not be the only approach used for evaluating precision of tests. Additional estimates of precision may include range of responses, minimum detectable differences compared to control survival or growth.

3.5 Model calculations

Precision of model outputs should be calculated by using each replicate data point rather than the average of the replicates. A minimum acceptable level of precision for the two models do not exist. However, if a sufficient number of replicates were tested, minimum acceptable levels of precision can be determined using a statistical test for outliers.

4. Completeness

Completeness is a measure of the amount of valid (i.e., meet or exceed the requirements of the project) samples collected or data obtained compared to the total amount necessary to make project decision(s) with confidence. Data completeness should be calculated as follows:

$$\% \text{ Completeness} = \frac{\text{Number of Valid Data or Samples}}{\text{Number of Data or Samples Planned}} \times 100$$

If completeness is less than stated, the sample or measurement may have to be repeated or best professional judgement used to assess the usefulness of the data for decision making purposes.

5. Representativeness

Representativeness expresses the degree to which data accurately and precisely represents a characteristic of a population, parameter variations at a sampling point, process condition, or an environmental condition. Representativeness is a qualitative parameter which is dependent upon proper choice of sampling design, and collection and testing protocols. Representativeness is maximized by performing all sampling and testing in a standardized manner, strictly adhering to procedures specified in the QAPP.

6. Comparability

Comparability expresses the confidence with which one data set can be compared with another. One way to ensure consistency is to require the use of similar procedures, SOPs, and standardized data forms. Data calculations and units should be consistent with the procedures and other organizations reporting similar data to allow for comparability. For laboratories, confidence in comparability can be enhanced by interlaboratory testing.

ATTACHMENT E-2
Guidance for Preparing Standard Operating Procedures

Standard operating procedures (SOPs) are written procedures that define how to carry out protocol-specified activities. Content may include, depending on the complexity and type of procedure:

General Information

- title and SOP number,
- version number and effective date,
- approval signature(s),
- serial page numbers and total number of pages, and
- person responsible for work (job title rather than name).

Procedural Information

- scope, application, and limitations of procedures,
- precautions, common problems, and interferences,
- facilities, equipment, organisms, and materials required (type, quality, and quantity),
- chronological description of required action steps and options for entire procedure from preparation through implementation and assessment to reporting,
- set-up, calibration, operation, and maintenance of ancillary equipment not part of the procedure's action steps,
- performance checks (type, frequency, acceptance criteria, corrective action),
- quality control checks (type, frequency, acceptance criteria, corrective action),
- recommended corrective and alternative actions (e.g. for equipment failure, procedural problems, documentation deficiencies, data anomalies, audit/inspection failures), and
- documentation requirements for each of the above.

The level of detail included depends mainly on the education, training, and experience of personnel. If written too restrictively, SOPs will need frequent revising. On the other hand, if the details are insufficient, instructions fail to provide adequate direction to study personnel. A compromise is to segregate all information that changes frequently as an appendix to the SOP, which may be easily updated.

SOPs for general activities (e.g. sample custody and sample collection) are typically less complex than SOPs for measurements.

ATTACHMENT E-3
Guidance for Preparing QAPPs

ELEMENT 1 "Title and Signature Page"

Page lists the project title, location of the site, project identification number, name of the QAPP preparer, for whom it was prepared, date prepared, and revision number. Signatures may include the project manager and QA personnel, field and lab managers and QA personnel, and Agency coordination personnel.

ELEMENT 2 "Table of Contents"

Table includes a serial listing of the 16 essential QAPP elements, tables, figures, attachments, references, and document distribution.

ELEMENT 3 "Project Description"

This project-specific information is likely to be provided in the Tier 1 evaluation and the DCP, and may be referenced. This element describes project scope and objectives, investigative approach, intended data use and associated data quality objectives, monitoring and sample network design and rationale, and project implementation issues and constraints.

Background information on the proposed dredging and disposal locations include:

- site specific features including location, size, borders, important physical features, topographic, geotechnical, geochemical and hydrodynamic data,
- historical contaminant data on sediments at the project,
- dredging and disposal history of the site,
- potential sources of contamination, and
- the list of contaminants of concern.

This information should be detailed in the Tier 1 evaluation report, and can be included in the QAPP by reference.

The scope of the proposed dredging project should be described, the decision to be made, and the data needed for a decision. The general design for data collection should be described, including:

- maps and tables documenting project monitoring and sample locations,
- management units delineation of the dredging site,
- methods and procedures for sample collection,
- methods and procedures for field measurements,
- the number and type of samples for each matrix,
- the number of samples for each parameter-matrix combination for all locations should include field blanks, spikes, and duplicates,
- testing scheduled for each sample, and the
- mechanism for making changes to the plan.

Individuals or organizations responsible for the implementation of sample collection and analysis should be identified, and limits on time and resources defined. These items, if fully described in the DCP or SOWs, can be included the QAPP by reference.

Data applications and modeling to be used in the evaluation should be identified along with data sources for input parameters.

The intended use of each type of data collected should be described and decision criteria identified. Project decisions and decision criteria for Great Lakes dredged material evaluations were detailed in the GLTEM and summarized in Section 3.3 of this appendix, and can be included in the QAPP by reference. Other decision criteria which need to be included in the QAPP are the appropriate State water quality standards and any project-specific criteria for Tier 4 testing.

ELEMENT 4 "Project Organization and Responsibility"

Project-specific information that must be provided in the QAPP include the following:

- key personnel/affiliation with planning, review, approval, implementation, and assessment authority,
- any special training or certification requirements for personnel in order to successfully complete the project task,
- lines of communication and authority between organizations and personnel, and
- a tentative schedule for preparation, review and approval of planning documents, data collection implementation, assessments and reporting,

Programmatic responsibilities of an organization that are provided in the organization's QAMP and project-specific

information contained in the DCP or other project planning documents may be included in the QAPP by reference.

ELEMENT 5 "Sampling and Measurement Quality Objectives"

The QAPP should include a description of project QA objectives, DQIs for field measurement data, sampling collection, laboratory measurements, model calculations or other types of data assessment as well as the means to achieve these objectives. This description should include:

- applicable technical, regulatory or project-required DQIs for each field and laboratory measurement for each sample matrix,
- how data quality will be measured and assessed to justify data usability,
- the type and frequency of internal QC samples and procedures, and
- how sample collection/handling, analysis, and reporting/ assessment ensure the representativeness and comparability of project samples and measurements.

The DQOs elaborated in the GLTEM and appendices can be included in the QAPP by reference. Project-specific DQOs, including DQIs and SOPs for new or modified procedures need to be described.

ELEMENT 6 "Sample Collection and Handling Procedures"

Information about sampling that must be provided in the QAPP include descriptions of the following:

- sampling equipment, any performance requirements and procedures for decontamination,
- sampling procedures, including field QC samples,
- criteria for retaining/discarding samples,
- sample containers and provisions to assure they are non-contaminated,
- sample packaging and shipment procedures, and
- procedures for sample homogenization and division.

This information, if detailed in the DCP or SOW can be included in the QAPP by reference.

ELEMENT 7 "Sample Documentation, Custody and Tracking"

Project-specific information that must be provided in the QAPP include descriptions of the following:

- project file, its location, custodian, storage and access procedures,
- sample numbering system and labeling method,
- how sampling activities will be documented,
- chain-of-custody procedures,
- sample receipt precautions and instructions,
- sample numbering system and labeling method for aliquoting bulk sample into individual sample containers (which may or may not be shipped to another lab),
- procedure(s) to ensure and document custody of the samples throughout the laboratory,
- laboratory sample storage conditions, and verification procedures,
- when and how to dispose of unused samples, and
- required subsequent corrective actions.

For most dredged material evaluations, these activities will be detailed in the organizational QAMP, DCP or contract SOW, and may be included in the QAPP by reference.

ELEMENT 8 "Calibration Procedures and Frequency"

For projects using field and laboratory methods in the GLTEM and appendices, these processes should be routine and may be included in the QAPP by reference. For modified or new methods, all tools, gauges, instruments, and other sampling, measuring, and test equipment that must be controlled and, at specified period, calibrated to maintain accuracy within specified limits should be identified. For each tool, gauge, instrument, or other equipment, the QAPP should:

- describe how to prepare standards and reagents,
- list the information concerning specific grades of material, appropriate glassware and containers for preparation and storage, and labeling and recordkeeping for stocks and dilutions should be included,
- describe the procedures for demonstrating proficiency for each method, including demonstrations of sensitivity, precision and accuracy of the method,
- define all terminology, procedures and frequency of determinations associated with the establishment of the sensitivity/MDL and the reporting limit,
- describe the initial and continuing calibration procedures (type of calibration, and concentration range and number of concentrations), calibration results and algorithm used to generate the calibration curve or response factor, initial and continuing calibration frequency, and initial and continuing calibration acceptance criteria, and
- indicate how calibration frequency, conditions, and

standards are documented and are traceable to the instrument.

ELEMENT 9 "Field and Laboratory Measurement Procedures"

The specific methods for field and laboratory measurements should be identified in the QAPP. For measurements made using the methods in the GLTEM and appendices, the methods can be included by reference. For measurements using new or modified methods, selected as discussed in Section 3.5, the following information should be included in the QAPP:

- an amendment to a standard method or a detailed SOP,
- cite by reference appropriate method validation data, or describe plans for conducting preliminary method validation studies as project subtasks if pertinent validation data are not available, and
- independent, validated, confirmatory methods for each critical measurement for which a multi-method confirmatory approach is applicable.

ELEMENT 10 "Internal Quality Control Checks"

Many of the field and laboratory methods detailed in the GLTEM and appendices include minimum QC procedures. These methods can be included in the QAPP by reference. For measurements using new or modified methods, or where QC procedures are not detailed, the following information should be included in the QAPP:

- identify all stages in sampling and measurement processes where internal QC checks are used to calculate the DQIs for sample collection, field measurements, laboratory analyses, and modeling efforts,
- describe or reference all specific QC samples and checks for each stage of field and laboratory activities, stating the frequency and required control limits for each QC sample or check,
- justify that QC procedures are compatible with the data specifications, and
- reference the required subsequent corrective action that should be described in detail in Element 15.

ELEMENT 11 "Data Reduction/Verification/Deliverables and Data Validation and Reporting"

Data reduction/verification, validation and reporting

procedures for approved laboratory methods are detailed in the GLTEM and appendices. These methods can be included in the QAPP by reference. For measurements using new or modified methods, or where data reduction/verification/validation procedures are not detailed in the GLTEM, the following information should be included in the QAPP:

- describe the reduction of field and laboratory raw data to final units, summarize reduction procedures, and any statistical approach used,
- describe the verification of field, laboratory and modeling results and summarize verification procedures,
- specify the reporting requirements for field, laboratory and modeling data, describe reporting format (including units), and content of data deliverable,
- describe the validation procedures for field, laboratory and modeling data, the criteria/guidelines/procedures to be used for data validation, and the procedures to determine outliers and define qualifying 'flags' used, and
- specify the format and content of data validation reports, any non-project specific reporting requirements, and annual reports.

The individual(s) responsible for data reduction/verification, validation and reporting should be identified in the QAPP.

ELEMENT 12 "Performance Audits and System Inspections"

Information about laboratory inspections and performance audits specific to the project data collection which should be provided include:

- specify the pre-award criteria and procedures,
- identify who is responsible for internal and external audits and inspections,
- specify the frequency of internal and external performance audits and system inspections,
- describe the audit and inspection procedures and criteria used to ensure work is performed as specified in the QAPP and that quality meet project requirements,
- reference the required subsequent corrective action, described in detail in Element 15, and
- specify the format and content of audit and inspection reports.

Routine procedures for performance audits and inspections for indefinite delivery laboratory contracts which are included in an organization's QAMP can be included in the QAPP by reference.

ELEMENT 13 "Equipment/Instrument Maintenance and Consumables Inspection"

These processes should be routine and, if documented in the organization's QAMP, SOPs or the DCP, may be included in the QAPP by reference. The information in these documents should include:

- identify the equipment and/or instruments requiring periodic maintenance (e.g. field monitors, sample equipment, laboratory equipment, and computer hardware),
- verify the availability of critical spare parts, necessary according to operating guidance or design specifications,
- describe the periodic preventative maintenance protocols for all equipment/instruments should be performed to ensure availability and satisfactory performance of the systems,
- discuss how repair of equipment/instruments will be performed (e.g. in-house, service contract),
- discuss how and by whom supplies and consumables are inspected and accepted for use in the project.
- identify the acceptance criteria for supplies and consumables in order to satisfy the technical and quality objectives of the project or task,
- discuss how inspections and acceptance testing, including use of QC samples, of environmental sampling and measurement systems and their components must be performed and documented to assure their use as specified by the design.
- identify and discuss how final acceptance of consumables is performed by independent personnel, and
- discuss how deficiencies will be resolved when acceptance criteria are not met, and how/when re-inspection occurs.

ELEMENT 14 "Procedures to Assess Data Usability"

The GLTEM and appendices provide considerable guidance on how to assess usability of data from approved methods. Assessing the usability of historic data is likely to require best professional judgement. Organizational QAMPs and SOPs may provide more specific procedures for assessing the usability of new or historic data. All of these procedures can be included in the QAPP by reference.

For data collection activities involving new or modified methods, and especially for any Tier 4 evaluations, the procedures for assessing data usability should be detailed in the QAPP, including the following information:

- describe the procedures to assess the usability of the samples collected, field and laboratory data, and
- discuss how issues will be resolved, by whom, and how

limitations on the data will be reported and used in decisions.

ELEMENT 15 "Corrective Action"

For projects using approved field and laboratory methods in the GLTEM and appendices, corrective action should be routine and may be included in the QAPP by reference. For new or modified methods, corrective actions should be defined in the SOP, including the following:

- list all activities potentially requiring corrective action during the course of the project,
- describe the mechanism to initiate, develop and approve corrective actions and identify the parties responsible,
- specify the predetermined limits for data acceptability beyond which corrective action is required for each procedure and/or measurement,
- describe the procedure to implement, document, and test effectiveness corrective actions, and
- specify the format and content of nonconformance reports and corrective action memos.

ELEMENT 16 "Quality Assurance Reports"

Procedures for QA reporting provided in organizational QAMPs can be included in the QAPP by reference. This information should include:

- identify the name and address of individuals submitting and receiving reports, number of copies and delivery date for draft and final QA reports,
- describe the type (e.g. written or oral, interim or final) and frequency of the QA report, and
- specify the contents of the various QA reports.

Project-specific information must always be provided in the QAPP.

ATTACHMENT E-4
Data Validation Guidance

1. Validation Activities

1.1 Check completeness and accuracy of deliverable

Field and laboratory deliverables should be reviewed to determine whether all documentation requirements in the QAPP, DCP and SOWs have been fulfilled. Complete records should exist for each activity. Emphasis on documentation helps assure sample integrity and sufficient technical information to recreate each event. Data validators are responsible for interacting with the data generator to obtain missing information and resolve data anomalies.

The results of the completeness check should be documented, and the data affected by incomplete records should be identified. Data validation cannot begin until the deliverable is complete.

1.2 Verify proper procedures followed

The data validator evaluates raw data and associated records to confirm all procedures were conducted according to the QAPP, DCP, and SOW. All deviations must be noted. The deliverable should be reviewed to verify:

- integrity and stability of samples,
- equipment operation and calibration,
- QC procedures and frequency,
- corrective action taken when necessary and was effective,
- internal verification performed, and
- calculations correct and no transcription errors exist.

1.3 Compare performance to acceptance criteria

Sensitivity/method detection limit, precision, and accuracy: The data validator quantitatively compares project results to acceptance criteria stated in the QAPP (element 5) and associated contract-SOWs and SOPs. Data not within control limits require corrective action, and the reviewer should check that corrective action reports, and the results of corrective action are available.

The data validator should determine whether samples associated with out-of-control quality control data are identified in a internal data verification report, and whether an assessment of the utility of such results is recorded.

The results, consequences, and documentation of performance and systems audits should also be considered in determining the validity of results.

Representativeness and comparability: The data validator qualitatively reviews field and laboratory records to detect problems affecting the representativeness and comparability of the data. Problems that may affect data representativeness are:

- choice of sample locations and subsamples,
- biases induced during field and laboratory preparation,
- exceedances of sample holding times,
- potential for contamination and degradation of sample during sample processing or analysis, and
- matrix interferences and effects.

The primary factor affecting data comparability is changes or modifications to sampling and analytical procedures specified in the QAPP and associated SOPs and contract-SOWs. The data validator assesses the consequences of these changes on the data. Conclusions should not be based on assumptions which cannot be tested and verified by data derived from the study.

2. Data Validation Report

Data validation reports identify samples and environmental data associated with poor or incorrect work. Data is either accepted or flagged with a qualifier. Qualifiers are letters which are placed next to the reported sample value to indicate there was, or could have been, a problem. Later, during data quality assessment, the reason for qualification should be considered when assessing the usability of qualified data.

Validation reports should include:

- case narrative describing any problems encountered and limitations on the use of the data, with a signature that authorizes the validation and release of the report,
- data assessment performed, including the number and type of samples evaluated, deviations from specified validation procedures, interpretation of test results and conclusions regarding the acceptability of data in terms of project objectives and method QA/QC,
- a summary of rejected samples or data,
- all qualifying flags used to mark the data in the validation report should be defined (a list typical data qualifiers is provided below), and
- a telephone record log and record of each communication.

Upon completion, data validation reports are forwarded to the PM for inclusion in the final report.

Data Qualifier Definitions

U	Nondetected. For chemical analysis, value reported is MDL.
J	Estimated results. Estimated data should be used with caution. For chemical analyses, concentrations between the MDL and LOQ are flagged with a "J".
R	Rejected due to deficiencies in the method or QC criteria.